RARS-DC个体化免疫调节技术

RARS-DC-V Personalized Immunomodulation Technology

Prof. Ronald Sarbacher

DC疫苗原理与安全性

Principle and Safety of DC-V

01

Stanman, the discoverer of DC cells, won the Nobel Prize.

2The 2011 Nobel Prize in Physiology or Medicine: Discovery of dendritic cells and their role in adaptive immunity

Ralph M. Steinman

The discoverer of dendritic cells (DC)

The discovery of dendritic cells laid an important foundation for modern research on antigen presentation and adaptive immunity.

DC细胞发现者斯坦曼获得诺贝尔奖

2011年诺贝尔生理学或医学奖：
发现了树突状细胞及其在适应性免疫中的作用

Ralph M. Steinman

树突状细胞（Dendritic Cell, DC）发现者

树突状细胞的发现，奠定了现代抗原呈递与适应性免疫研究的重要基础。

1 millimeter: The critical threshold for clinical tumor detection

The cognitive transition from the sub-millimeter latent period to the clinically observable period

01

The detection limit of modern medicine

Modern medical technology has an objective lower limit in the clinical identification of tumors. Most conventional imaging examinations have limited ability to detect sub-millimeter lesions. Usually, it is only when the tumor is close to or exceeds 1 millimeter that it gradually enters the range of clinical visibility.

02

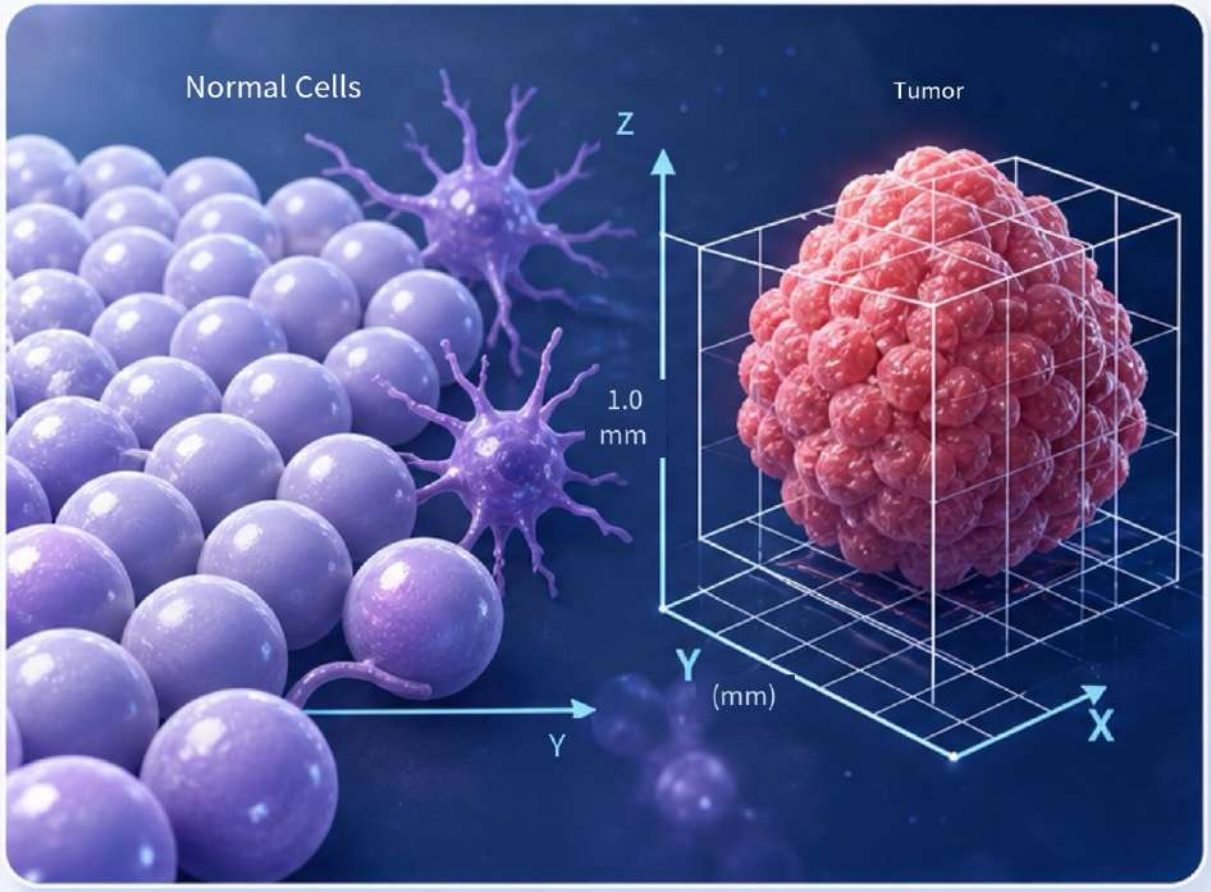
The latent stage at the sub-millimeter level

One millimeter represents a crucial dividing line between clinical detection and the early concealment of tumors. Many tumors are difficult to be detected in the sub-millimeter stage (less than 1 millimeter), which is precisely the core challenge faced by early diagnosis.

03

The correlation between tumor size and cell quantity

Generally speaking, a tumor with a diameter of approximately 1 millimeter would contain around 1 million cancer cells. This quantitative relationship helps us understand the growth scale of the tumor at the microscopic level.



Ammeter: 1 millimeter is not the starting point of tumor formation; rather, it is the point at which modern clinical tests have a greater chance of "detecting" it.

1毫米：肿瘤临床检测的关键分水岭

从亚毫米隐匿期到临床可见期的认知转换

01

现代医疗的检测极限

现代医疗技术对肿瘤的临床识别存在客观下限。
多数常规影像学检查对亚毫米病灶的识别能力有限，
通常在肿瘤接近或超过1毫米时，才逐渐进入临床可见范围。

02

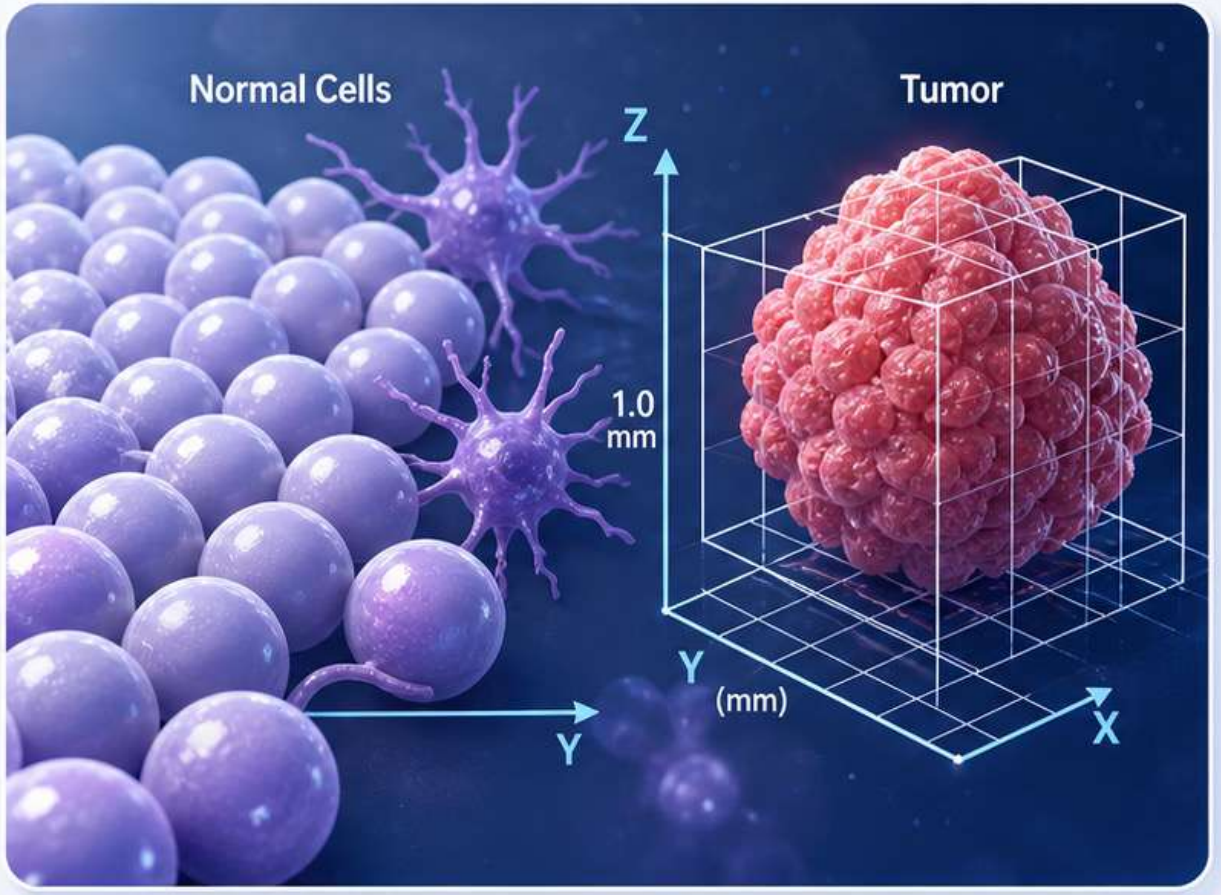
亚毫米阶段的隐匿性

1毫米是临床检测与肿瘤早期隐匿之间的重要分水岭。
许多肿瘤在亚毫米阶段（小于1毫米）往往难以被及时发现，
这正是早期诊断面临的核心挑战。

03

肿瘤大小与细胞数量的关联

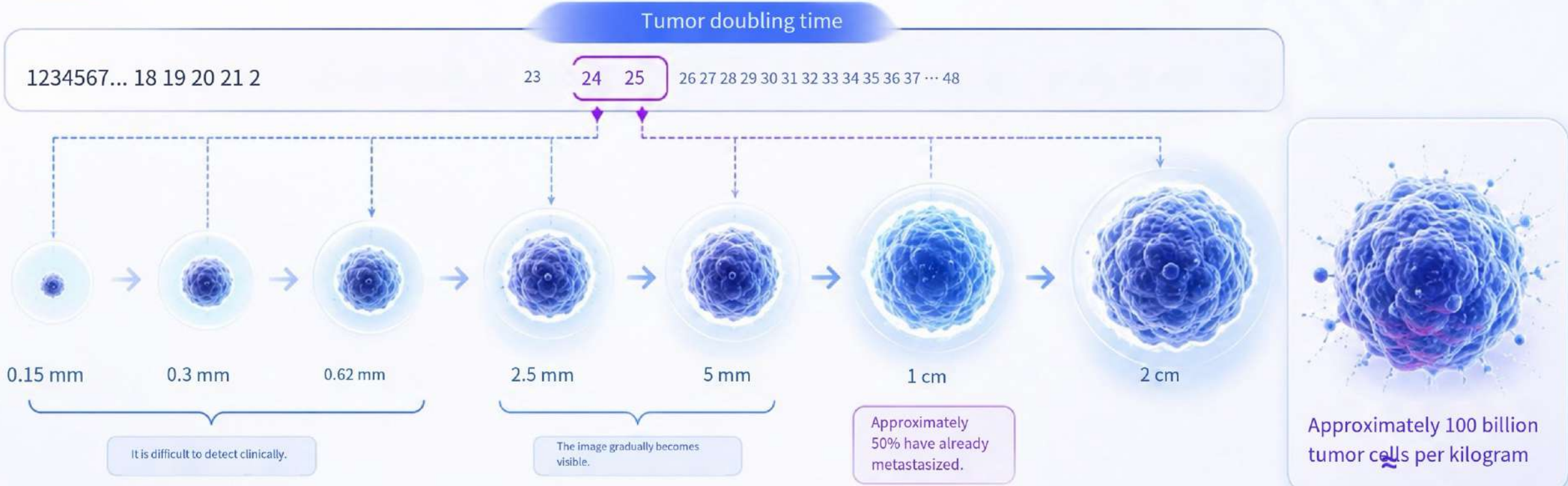
一般估算，直径约1毫米的肿瘤，其细胞数量大约相当于100万个癌细胞的集合。这一量化关系有助于理解肿瘤在微观层面的生长规模。



提示： 1毫米并不是肿瘤发生的起点，而是现代临床检测更有机会“看见”它的起点。

Tumor doubling time and volume evolution

The key process from the sub-millimeter latent stage to the clinically observable stage



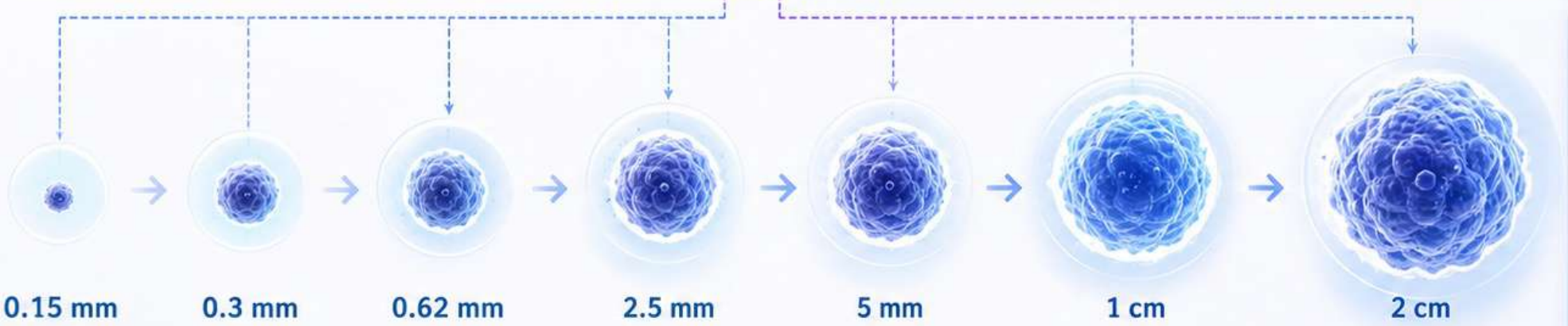
Before a tumor is detected by imaging, it usually undergoes a prolonged process of cell division.

肿瘤倍增时间与体积演变

从亚毫米隐匿期到临床可见期的关键过程

肿瘤倍增次数

1 2 3 4 5 6 7 … 18 19 20 21 22 23 **24 25** 26 27 28 29 30 31 32 33 34 35 36 37 … 48

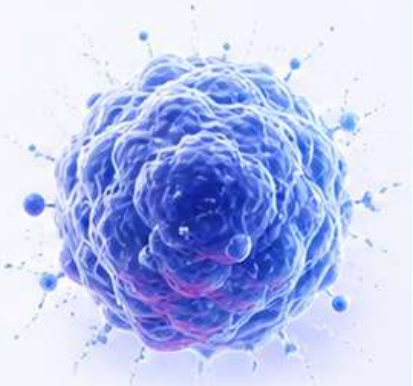


0.15 mm　0.3 mm　0.62 mm　2.5 mm　5 mm　1 cm　2 cm

临床难以发现

影像逐渐可见

约50%
已发生转移



约1000亿肿瘤细胞
≈ 1 kg

隐匿生长期 → 影像可见期 → 转移风险上升 → 临床负荷加重

提示：肿瘤在被影像发现之前，往往已经历较长时间的倍增过程。

This is a medical revolution originating from the "internal awakening" of the body. What truly determines the outcome is never the treatment itself, but whether the body has the ability to carry out an endogenous immune response. DC vaccines are also the core pillar technology of personalized immunotherapy.

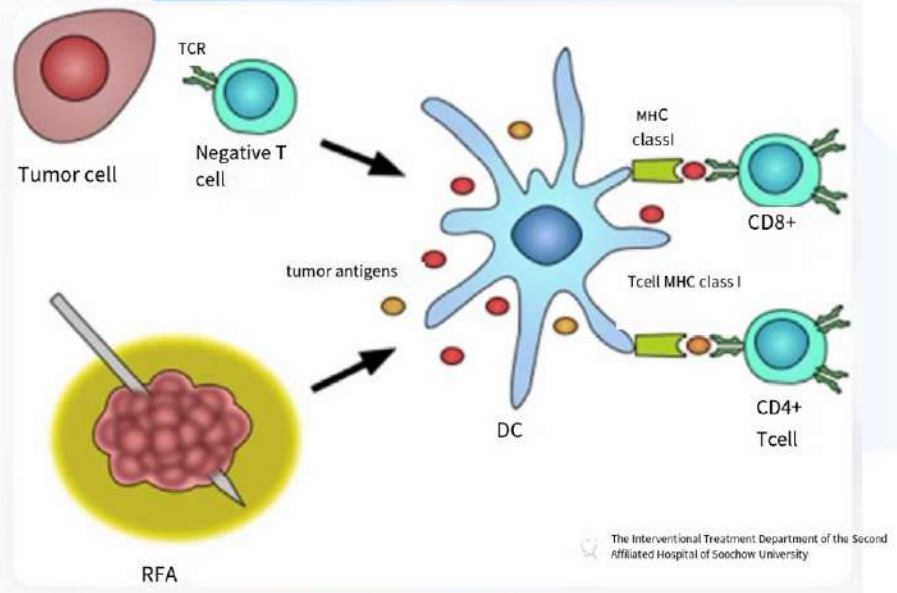
White blood cell

- Lymphatic system. (Adaptive immunity)
  - ILC
  - NK. Does not recognize specific antigens
  - T (accounts for 70% of the lymphatic system)
    - Expressing antigen receptors, upon contact with antigenic determinants, they differentiate into effector T cells.
  - B
    - After being exposed to the antigen, it transforms into plasma cells (which secrete antibodies)

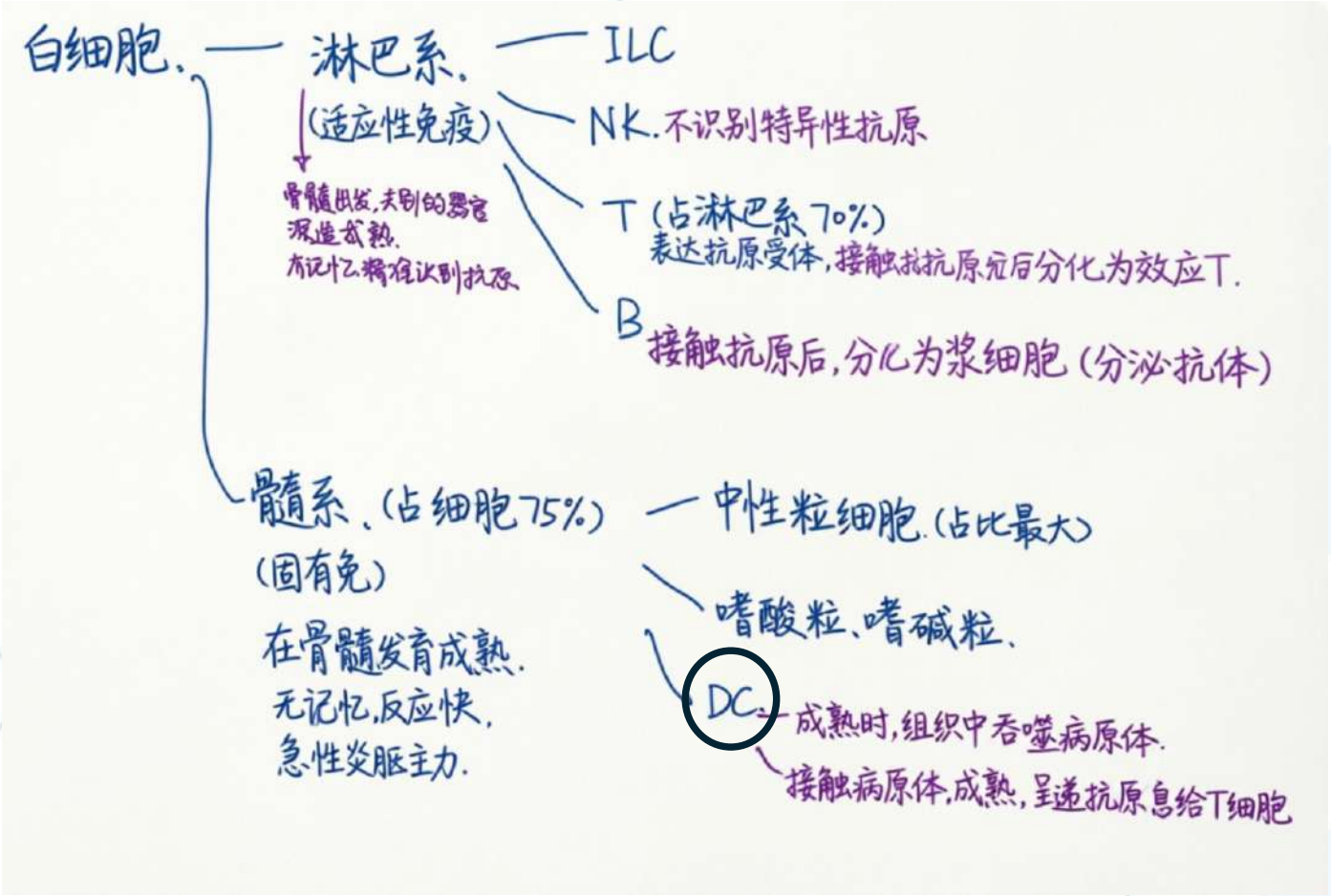
Starting from the bone marrow, other officials have created a detailed account of my life, with precise memories of every detail. This account also includes the identification of various antigens.

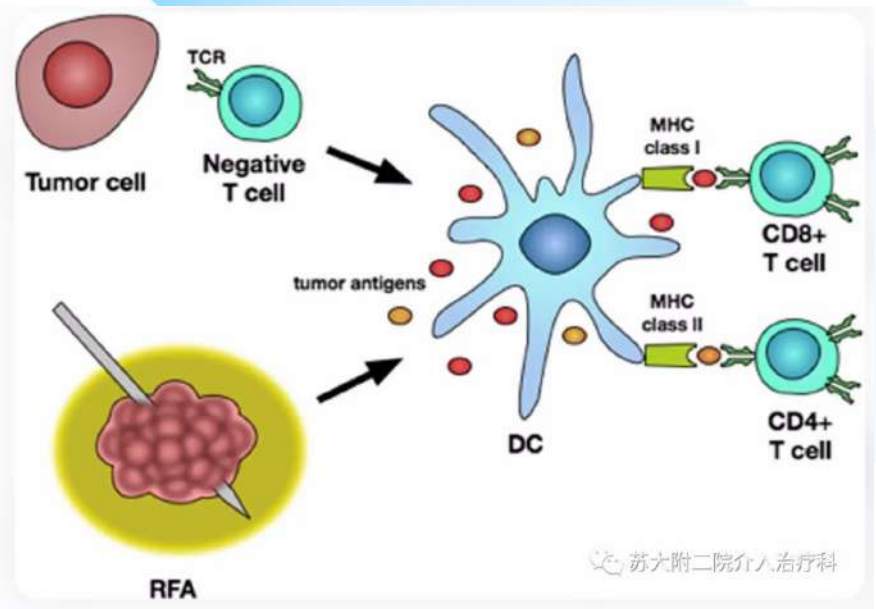
- Myeloid (accounting for 75% of cells) (innate immunity)
  - Neutrophils (accounting for the largest proportion)
  - Eosinophils, basophils.
  - DC
    - When mature, the cells engulf the pathogens.
    - Contact with the pathogen, maturation, presentation of antigens to T cells

In the mature bone marrow, there is no memory, quick response, and it is the main force in acute inflammatory brain conditions.



这是一场来自身体“内部觉醒”的医学革命，真正决定结局的，从来不是治疗本身，而是机体有没有能力完成一场内源性的免疫反应。DC疫苗也是个性化免疫疗法的核心支柱性技术。

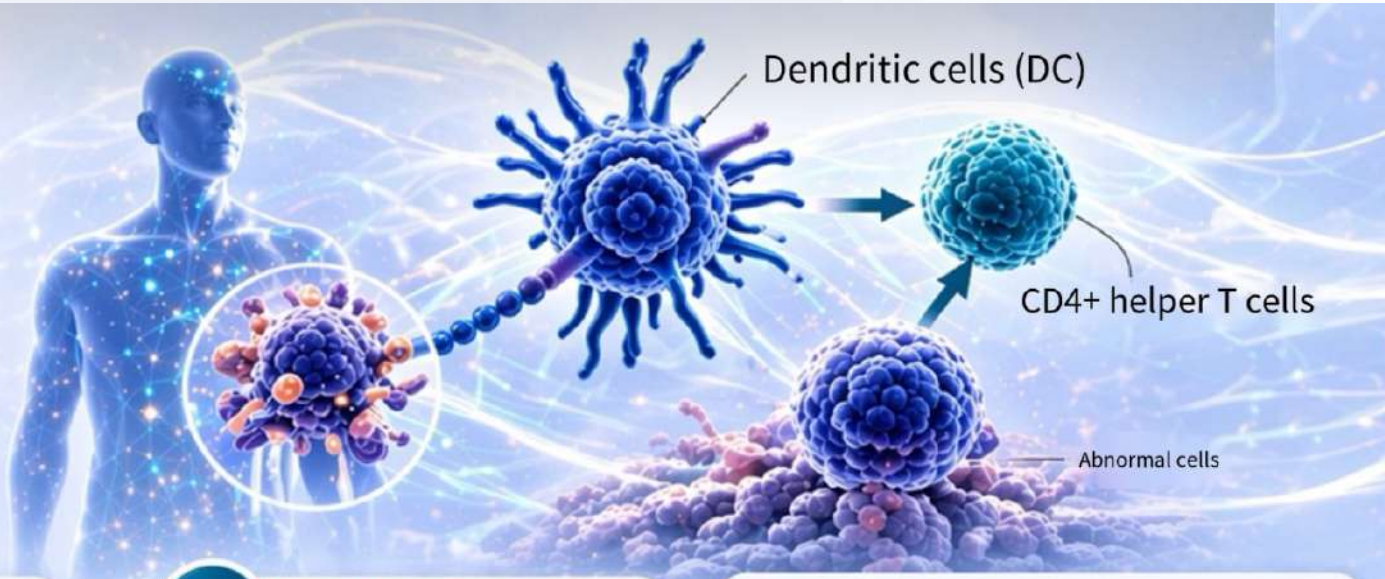




How does the DC-V vaccine prevent cancer?

Train the immune system to recognize and eliminate abnormal cells

The DC-V vaccine enhances the immune system's ability to identify and eliminate abnormal cells at an early stage, establishing a long-term immune surveillance mechanism. This helps to reduce the risk of cancer occurrence and recurrence.



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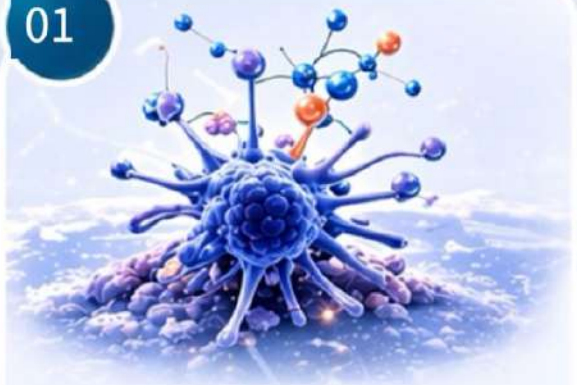
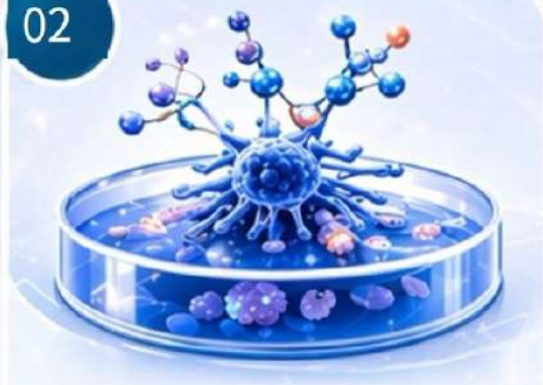


Antigen information collection is carried out in a controlled experimental environment, which induces the maturation of dendritic cells and loads specific antigen information related to abnormal cells.

02



Reinfusion and immune activation involve reintroducing mature dendritic cells back into the body, which then activate CD4+ helper T cells and CD8+ cytotoxic T cells, initiating an immune response against abnormal cells.

03

Immune memory and continuous monitoring establish long-term immune memory, enabling the immune system to continuously monitor and eliminate abnormal cells at an early stage.

The core advantage of the DC-V vaccine

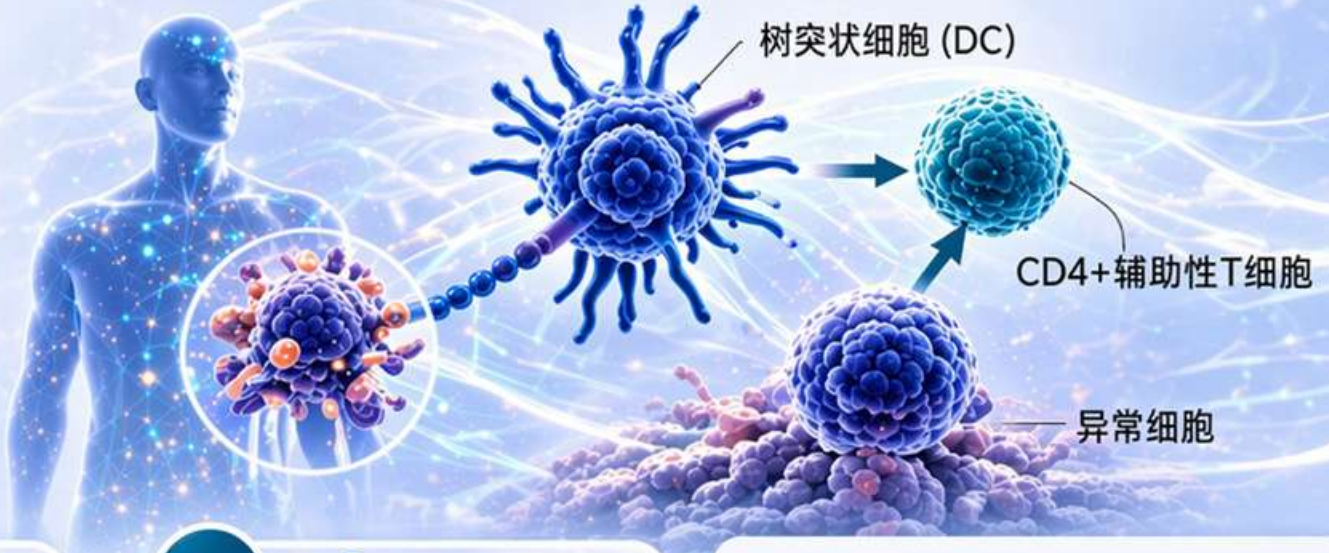
- Early identification of abnormal cells
- Enhance the ability of immune surveillance
- Providing long-term protection through immune memory
- Realize individualized and precise immune activation
- Help to reduce the risk of cancer occurrence and recurrence

The DC-V vaccine activates the body's own immune system, enabling it to recognize and eliminate

DC-V疫苗如何预防癌症

训练免疫系统识别并清除异常细胞

DC-V疫苗通过训练免疫系统，及早识别并清除异常细胞，
建立长期免疫监视机制，从而有助于降低癌症发生与复发风险。



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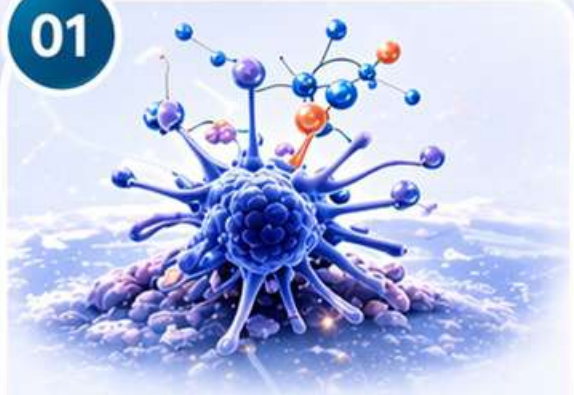


抗原信息采集

在受控实验环境中，诱导树突状细胞成熟，并加载与异常细胞相关的特异性抗原信息。

02

回输与免疫激活

将成熟后的树突状细胞回输体内，激活CD4+辅助性T细胞及CD8+细胞毒性T细胞，启动针对异常细胞的免疫应答。

03

免疫记忆与持续监测

建立长期免疫记忆，使免疫系统能够持续监测并在早期清除异常细胞。

DC-V疫苗的核心优势

- 及早识别异常细胞
- 增强免疫监视能力
- 通过免疫记忆提供长期保护
- 实现个体化、精准化免疫激活
- 有助于降低癌症发生与复发风险

DC-V疫苗通过激活人体自身免疫系统，使机体在癌症发生前即具备识别和清除异常细胞的能力，从而构建面向未来的长期免疫防护。

DC vaccine system

DC-T (therapeutic) versus DC-V (preventive)

Dendritic cells (DCS) train the immune system to recognize and remember abnormal cells.

DC-T (therapeutic type)

For existing tumors and abnormal lesions

Precision immune clearance

Comparison

DC-V (preventive)

Protection for high-risk and precancerous states

Long-term immune surveillance

DC-T is used for precision treatment

Clear existing tumor cells and abnormal cells through targeted immune activation.

DC vaccine system

Two complementary strategies, one common goal: building a more robust tumor immune defense line.

DC-V is used for long-term prevention

Build a lasting immune memory to identify and clear abnormal cells early, thereby reducing the risk of tumor development.

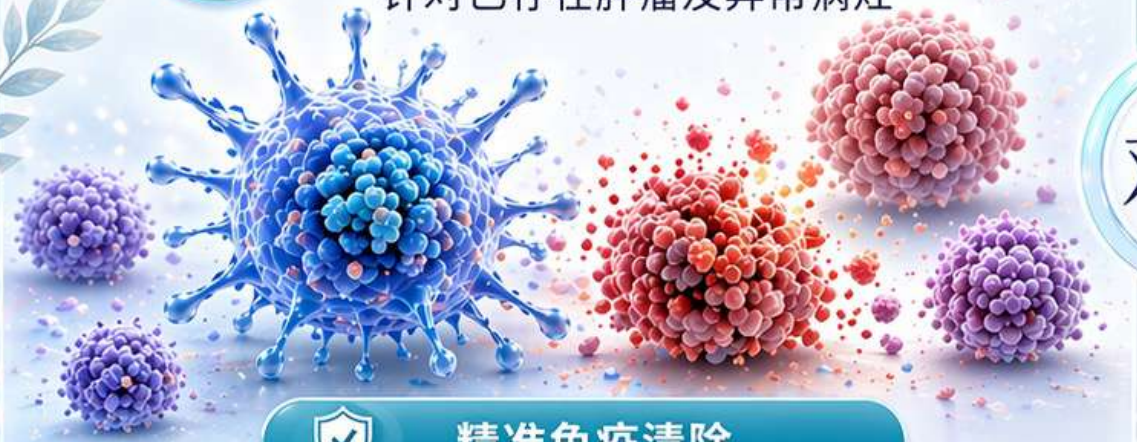
DC疫苗体系：

DC-T（治疗型）与 DC-V（预防型）

树突状细胞（DC）可训练免疫系统识别并记忆异常细胞。

DC-T（治疗型）

针对已存在肿瘤及异常病灶

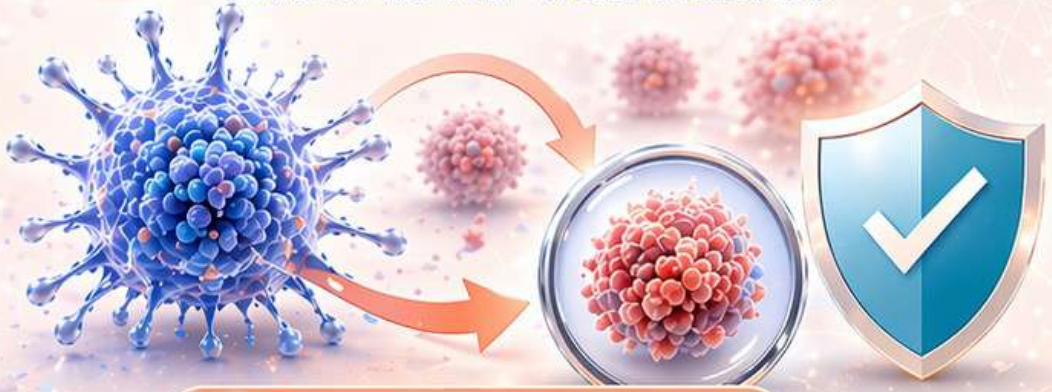


精准免疫清除

对比

DC-V（预防型）

面向高风险状态与癌前状态的防护



长期免疫监测

DC-T用于精准治疗

通过定向免疫激活，清除已存在的肿瘤细胞与异常细胞。

DC疫苗体系

两种互补策略，一个共同目标：构建更稳健的肿瘤免疫防线。

DC-V用于长期预防

建立持久免疫记忆，及早识别并清除异常细胞，从而降低肿瘤发生风险。

Biological mechanism

The core role of DC-V

Dendritic cells are the key cells for immune recognition and information integration. RARS-DC-V emphasizes that in non-tumor treatment scenarios, by optimizing antigen recognition, information transmission, and immune synergy, the ability to enhance the early perception and immune response organization of the body to abnormal changes can be improved, providing a foundation for maintaining immune homeostasis.

Individualized immune regulation pathway

RARS-DC-V is based on the assessment of individual immune status. By optimizing the antigen presentation and immune guidance functions of DCs, it promotes the coordination among T cells, NK cells and regulatory networks, avoiding strong stimulating activation, and constructing a milder and more balanced immune regulation pathway.

Steady-state maintenance orientation

The key technical aspect lies in restoring immune recognition, reducing the risks of chronic inflammation and immune imbalance, and enhancing the body's self-monitoring and repair capabilities through gentle regulation. The core objective is to maintain the stability of the internal environment, serving the management of high-risk populations, postoperative maintenance, and healthy immune management.

生物学机制

DC-V的核心角色

树突状细胞是免疫识别与信息整合的关键细胞。RARS-DC-V强调在非肿瘤治疗场景下，通过优化抗原识别、信息传递与免疫协同，提升机体对异常变化的早期感知与免疫应答组织能力，为免疫稳态维护提供基础。

个体化免疫调节路径

RARS-DC-V以个体免疫状态评估为基础，通过优化DC的抗原呈递和免疫引导功能，促进T细胞、NK细胞及调节性网络之间的协调，避免强刺激性激活，构建更温和、更平衡的免疫调节路径。

稳态维护导向

技术重点在于恢复免疫识别、降低慢性炎症与免疫失衡风险，并通过温和调节提升机体自我监测与修复能力。其核心目标是维持内环境稳定，服务于高风险人群管理、术后维持及健康免疫管理。

RARS-DC-V禁忌症与注意事项

Contraindications and Precautions

02

RARS-DC-V Population Assessment and Pre-Implementation Inspection

Based on the assessment of blood routine, liver and kidney function, electrolytes and inflammatory status, the safety and suitability of immune regulation intervention are judged.

1) Basic blood routine assessment

A complete blood count test must be conducted, with particular attention paid to the levels of white blood cells, lymphocytes, hemoglobin and platelets. This is to assess the feasibility of blood collection, immune status and the risk of bleeding.

(2 Initial screening of immune status

Combining the levels of white blood cells and lymphocytes, the initial assessment of the body's immune activity and basic defense capacity can be made. If there are obvious signs of infection or immune imbalance, the cause should be identified first.

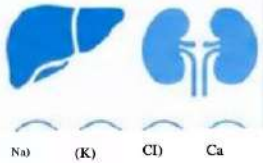
3 Anemia and Oxygen Supply Capacity Assessment

Abnormal hemoglobin levels suggest the possibility of anemia, chronic wasting, or a decline in overall tolerance. It is necessary to assess whether it affects blood collection, tolerance to reinfusion, and the safety of subsequent interventions.

4 Identification of Coagulation and Platelet Risks

For patients with thrombocytopenia or abnormal coagulation function, the risks of blood collection, injection and local reactions should be evaluated with particular attention. If necessary, coagulation function tests should be supplemented before deciding whether to proceed.

5 Evaluation of liver and kidney function and electrolytes



ALT, AST, bilirubin, creatinine, urea nitrogen and electrolytes are used to assess metabolic capacity, detoxification ability and overall tolerance. When there are significant abnormalities, the underlying issues should be addressed first.

6 Inflammation and Timing of Implementation Judgment

CRP, ESR and infection-related indicators are used to identify a state of high inflammatory response. When there is acute infection, fever or a significant increase in CRP, the implementation of RARS-DC-V should, in principle, be postponed.

Core Objectives of the Pre-Implementation Assessment of DC-V

Confirm whether it is suitable to enter the immune regulatio n pathway.

Hemoglobin rec ognition for blood collection and reinfusion Relevant risks

Judging the metabolic and tolerance basis of the body to

ensure the safety of the implementation timing,

reasonable and controllable

Expert decision-making principle

- Give priority to safety over progress.
- Support population stratification with basic examinations
- Abnormal indicators should be evaluated and treated first, and then the final decision should be made by the clinician based on the overall condition.

i说明: RARS-DC-V属于免疫调节路径,适用人群评估应基于实验室检查、症状状态、基础疾病与临床获益-风险平衡综合判断。

RARS-DC-V 人群评估与实施前检查

以血常规、肝肾功能、电解质与炎症状态评估为基础，判断免疫调节干预的安全性与适配性

1 血常规基础评估

必须完成血常规检测，重点关注白细胞、淋巴细胞、血红蛋白及血小板水平。用于判断采血可行性、免疫状态及出血风险。

2 免疫状态初筛

结合白细胞与淋巴细胞水平，初步判断机体免疫活性与基础防御能力。若存在明显感染或免疫失衡信号，应先明确原因。

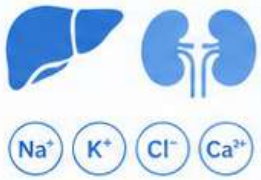
3 贫血与供氧能力评估

血红蛋白异常提示可能存在贫血、慢性消耗或整体耐受性下降。应评估是否影响采血、回输耐受及后续干预安全性。

4 凝血与血小板风险识别

血小板减少或凝血功能异常者，需重点评估采血、注射及局部反应风险。必要时补充凝血功能检查后再决定是否实施。

5 肝肾功能与电解质评估



ALT、AST、胆红素、肌酐、尿素氮及电解质用于评估代谢能力、排毒能力与整体耐受性。明显异常时应先处理基础问题。

6 炎症与实施时机判断

CRP、ESR及感染相关指标用于识别炎症高反应状态。急常摭染、发热或CRP显著升高时，RARS-DC-V原则上应暂缓实施。

DC-V实施前评估核心目标

确认是否适合进入免疫调节路径

识别采血与回输相关风险

判断机体代谢与耐受基础

确保实施时机安全、合理、可控

专家决策原则

- 以安全性优先于进度
- 以基础检查支持人群分层
- 异常指标先评估、先处理、再决定
- 最终由临床医生结合整体状况综合判断

说明：RARS-DC-V属于免疫调节路径，适用人群评估应基于实验室检查、症状状态、基础疾病与临床获益-风险平衡综合判断。

Contraindications and Precautions of RARS-DC-V

With safety assessment, indication judgment and risk-benefit balance as the core

Severe organ dysfunction (use with caution)

Patients with significantly impaired heart, lung, liver, and kidney functions have reduced treatment tolerance and limited room for managing adverse reactions. Organ function assessment must be completed before implementation, and the suitability for intervention should be comprehensively determined by the clinician.

Severe allergy history (use with caution)

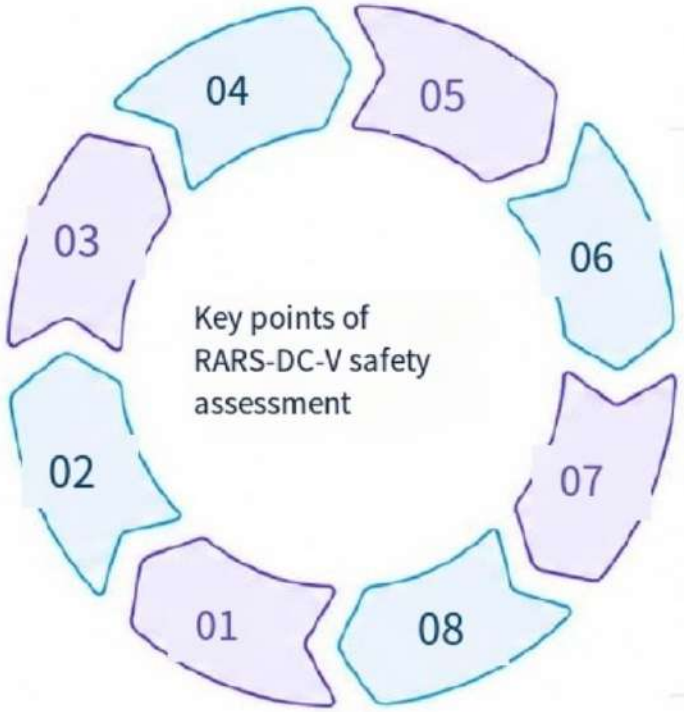
For individuals with a clear history of severe allergic reactions to the relevant reagents, excipients, or previous biological products, a detailed allergy history screening should be conducted. If necessary, the implementation should be postponed to avoid triggering severe allergic events.

Active autoimmune diseases (use with caution)

When systemic lupus erythematosus, rheumatoid arthritis and other autoimmune diseases are in the active stage, the immune homeostasis has been disturbed. At this time, immune intervention may increase the risk of disease fluctuations. It is recommended to make a decision after a specialist assessment.

Acute infection/fever stage (postpone)

When there is an active bacterial, viral or fungal infection, or when accompanied by fever, abnormal white blood cells, or a significant increase in CRP, it is not advisable to proceed immediately. The infection and inflammation should be controlled first, and then the timing of the intervention should be reassessed.



Abnormal coagulation or anticoagulation therapy (evaluation)

Patients with significantly reduced platelets, abnormal coagulation function, or those undergoing anticoagulant therapy are at risk of bleeding during both blood collection and injection. Coagulation assessment should be completed and a risk control plan established before the procedure.

High inflammatory response state (on hold)

Significantly elevated CRP, ESR or other inflammatory markers suggest that the body is in a hyper-reactive or stressed state. At this stage, implementing immunomodulation may increase unpredictability. It is advisable to first identify the cause and stabilize the condition.

3

Pathway for Re-evaluation of Active Malignant Tumors

RARS-DC-V is positioned for immune monitoring and risk management. For those with confirmed active malignant tumors, it is not advisable to simply follow the DC-V pathway. They should be referred to a tumor specialist for assessment, and if necessary, consider more appropriate treatment pathways such as DC-T.

Safety prerequisites before reinfusion (must be met)

Before implementation, a medical history collection, physical assessment, blood routine test, infection indicators, coagulation function and necessary organ function tests should be completed, and informed consent should be obtained. Safety assessment should take priority over treatment progress.

+说明:以下内容以暂缓、慎用和实施前评估为主;是否实施应由临床医生结合适应证、实验室指标与整体获益综合判断。

RARS-DC-V 禁忌症与注意事项

以安全评估、适应证判断与风险获益平衡为核心

器官功能严重不全（慎用）

心、肺、肝、肾功能明显受损者，治疗耐受性下降，不良反应处理空间有限。实施前需完成器官功能评估，并由临床医生综合判断是否适合干预。

严重过敏史（慎用）

对制备相关试剂、辅料或既往生物制品存在明确严重过敏反应者，应进行详细过敏史筛查。必要时暂缓实施，避免诱发严重过敏事件。

活动性自身免疫病（慎用）

系统性红斑狼疮、类风湿关节炎等处于活动期时，免疫稳态已受扰动。此时进行免疫干预可能增加病情波动风险，建议在专科评估后决定。

急性感染/发热期（暂缓）

当存在细菌、病毒或真菌感染活动期，或伴发热、白细胞异常、CRP显著升高时，不宜立即实施。应先控制感染与炎症，再评估介入时机。

凝血异常或抗凝治疗（评估）

血小板明显减少、凝血功能异常，或正在接受抗凝治疗者，采血与注射环节均存在出血风险。实施前应完成凝血评估并明确风险控制方案。

炎症高反应状态（暂缓）

CRP、ESR或其他炎症指标显著升高，提示机体处于高反应或应激状态。此阶段实施免疫调节可能增加不可预测性，宜先查明原因并稳定病情。

活动性恶性肿瘤需重评路径

RARS-DC-V定位于免疫监测与风险管理。对于已明确活动性恶性肿瘤者，不宜简单按DC-V路径处理，应进入肿瘤专科评估，必要时考虑DC-T等更匹配的治疗路径。

回输前安全前提（必须满足）

实施前应完成病史采集、体格评估、血常规、感染指标、凝血功能及必要的器官功能检查，并完成知情同意。安全性评估应优先于治疗进度。

说明：以下内容以暂缓、慎用和实施前评估为主；是否实施应由临床医生结合适应证、实验室指标与整体获益综合判断。

DC疫苗的使用流程

Basic Workflow of RARS-DC

03

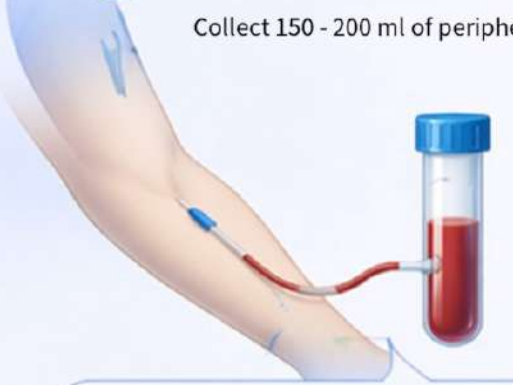
RARS-DC-T Laboratory Flowchart

RARS-DC-T Laboratory Preparation Process

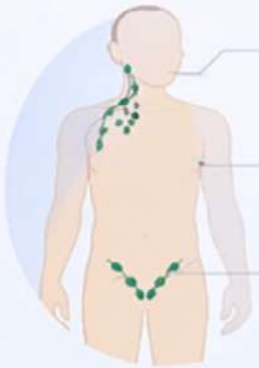
The patient-centered personalized DC vaccine preparation process

01 Personalized one-on-one collection

Collect 150 - 200 ml of peripheral blood



Subcutaneous injection (DC reinfusion route)



Cervical lymph nodes (located below the neck)

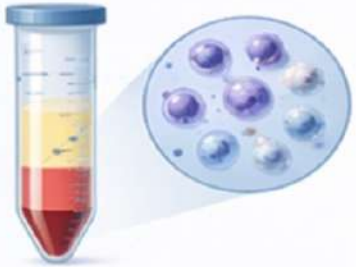
Axillary lymph nodes
Axillary Lymph Nodes

Inguinal Lymph Nodes

Safety level coefficient: Level 1

02 And antigen loading

Isolation of PBMC
(Precursor cells in peripheral blood)



DC performs antigen loading

Tumor lysate
Specific tumor antigen
Viral peptide segments, etc.

03 Induction of differentiation and maturation

Extracellular culture induction

Day1

Immature DC

Maturation Factor Cytokine Cocktail

Day2-Day6 成熟
DC Mature DC

GMP
Standard laboratory
Quality Control

04 Purify and collect DC

Day7

Collection, washing, quality inspection, and preparation are completed.

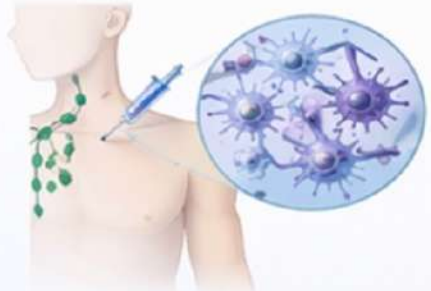
1 ml reinfusion

1 ml of cryopreservation solution

05 Reinfusion

Day 7 (or Day 8)

Subcutaneous / Lymph node injection



Mechanism of action

Activate T cells
Initiate specific immune response

Precise identification
Targeted elimination of tumor cells

Individualized customization enhances therapeutic efficacy and reduces side effects.

RARS-DC-T: Scientific rigor · Personalized customization · Precise immunity

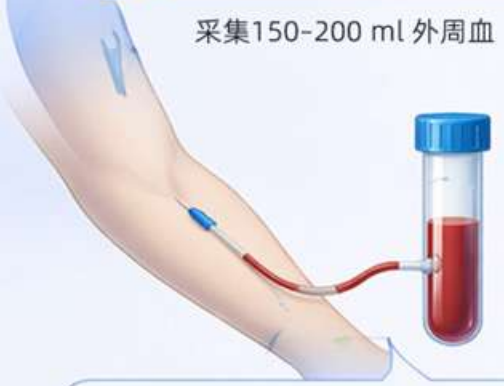
RARS-DC-T 实验室流程图

RARS-DC-T 实验室制备流程

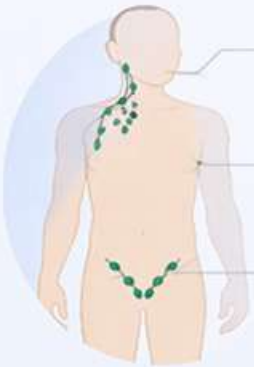
以患者为中心的个性化DC疫苗制备流程

01 个性化一对一采集

采集150-200 ml 外周血



皮下注射（DC回输途径）



颈下淋巴区
Cervical Lymph Nodes

腋下淋巴结
Axillary Lymph Nodes

腹股沟淋巴结
Inguinal Lymph Nodes

安全等级系数：一级别

02 并抗原负载

分离PBMC
（外周血单个核细胞）

DC进行抗原负载

肿瘤裂解物
特异性肿瘤抗原
病毒肽段等

03 诱导分化与成熟

体外培养诱导

Day1
未成熟DC
Immature DC

成熟因子
Cytokine
Cocktail

Day2-Day6
成熟DC
Mature DC

GMP
标准实验室
质量控制

04 提纯并收集DC

Day7
收集、 洗涤 、质检、
制备完成

1 ml 回输
1 ml 冻存

05 回输

Day7（或 Day8）
皮下 / 淋巴结注射

作用机制

激活T细胞
启动特异性免疫反应

精准识别
定向清除肿瘤细胞

个体化定制
提高疗效，降低副作用

RARS-DC-T：科学严谨 · 个性定制 · 精准免疫

DC疫苗制备及GMP管理

标准化制备流程 · 严格GMP管理 · 保障产品质量与安全

05

The professionalism and safety of the Thios DC preparation process

01 Strict management of sample source: collection of peripheral blood from the subject, identity verification, and double-person verification throughout the process, with complete traceability of the samples.

02 Standardized experimental environment monitoring for the aseptic preparation professional system. Key consumables and culture systems are under controlled operation. Operators undergo professional training before taking up their positions.

03 Standardized Process Control

Isolation of individual nucleated cells

The DC induction, maturation and antigen loading process is clear.

The key parameters can be replicated and scaled up.

04 Quality Release: Multiple Checks on Cell Viability, Quantity and Morphology; Sterility, Endotoxin and Other Release Tests; When necessary, combine phenotypic and functional validations.

05 Clinical application: Risks are controllable, return routes are clear. Pre-return assessment and post-return observation are standardized.

Improvement of adverse reaction monitoring and emergency handling mechanisms

06 Targeted Population Screening for Adaptation

The indications and contraindications will be evaluated by the doctor.

Do not blindly apply it to people who are not suitable for it.

Emphasize individualization, standardization and evidence-based approach

Core value: Professional production ensures quality, standardized procedures guarantee safety.

塞奥思DC制备的专业性与安全性

01 严格的样本来源管理

自体外周血采集

身份核验与双人复核

样本全程可追溯

02 无菌制备专业体系

规范化实验环境监测

关键耗材与培养体系受控

操作人员经专业培训上岗

03 标准化工艺控制

单个核细胞分离

DC诱导、成熟与抗原负载流程清晰

关键参数可复制、可放大

04 质量放行多重把关

细胞活率、数量与形态评估

无菌、内毒素等放行检测

必要时结合表型与功能验证

05 临床应用风险可控

回输路径明确

回输前评估与回输后观察规范

不良反应监测与应急处理机制完善

06 适应人群审慎筛查

由医生评估适应证与禁忌证

不针对不适宜人群盲目应用

强调个体化、规范化、循证化

核心价值：专业制备决定质量，规范流程保障安全。

Sample transportation and handover, laboratory standardization preparation, and comprehensive quality inspection

Cell therapy process

01

Sample collection management: The samples are kept under temperature control throughout the collection process to prevent them from deteriorating.

The identification is clear and the records are complete, ensuring traceability.

02

The preparation process is carried out in a clean environment to avoid the risk of contamination.

Follow the standard procedures to ensure consistency in the preparation.

03

Cell separation and culture were carried out to isolate PBMC, and then directed induction and maturation regulation were performed.

Complete the washing and preparation process, and obtain a stable DC cell preparation.

04

Quality control measures are used to monitor the number and viability of cells, ensuring their effectiveness. The phenotypic characteristics are examined to confirm the correct functionality of the cells.

Conduct aseptic and endotoxin tests to ensure safety.

05

The formulation can be used in clinical practice only after all the indicators meet the standards for release.

Strictly control the release process to prevent substandard products from being released.

06

Clinical reinfusion guarantee ensures the safety and efficacy of the preparations, and supports patient treatment.

Full-process monitoring to enhance the reliability of clinical application.

样本运输交接、实验室标准化制备，及全面质量检测

细胞治疗流程

01

样本采集管理

采集后全程温控，
防止样本变质。

标识清晰记录完整，
确保可追溯性。

02

制备环境控制

在洁净环境中操作，
避免污染风险。

遵循标准程序，
保证制备一致性。

03

细胞分离培养

分离PBMC并进行
定向诱导与成熟调控。

完成洗涤配制，
获得稳定DC细胞制剂。

04

质量检测控制

检测细胞数量与活率，
确保有效性。

检查表型特征，
确认细胞功能正确。

进行无菌和内毒素检测，
保障安全性。

05

制剂放行标准

所有指标合格后方可
进入临床使用。

严格把关放行流程，
防止不合格产品流出。

06

临床回输保障

确保制剂安全有效，
支持患者治疗。

全流程监控，
提升临床应用可靠性。

Why are the Theoys system vaccines safer?

RARSIG MEDICAL GROUP

It is not a single-cell product, but a set of individualized immunological platforms that are traceable, controllable and verifiable.

01 Reduction of immune risk through autologous sources

- Based on the dynamic antigen information of the patient's own peripheral blood and autologous plasma
- Reduce the risks of rejection, immune recognition and exogenous interference caused by foreign sources
- Higher biocompatibility, more in line with the logic of individualized immune management

02 The German GMP standards ensure the controllability of the preparation process.

- Establish the preparation system based on the German/European GMP principles
- The entire process of environment, equipment, consumables, personnel, records and batch management is under control.
- Minimize human error, pollution risks and batch fluctuations to the greatest extent

03 The SOP process in Germany ensures that there are standards for every step.

- From blood collection, sample reception, PBMC separation, DC induction and maturation, quality control testing to reinfusion and release
- All have standardized operation procedures.
- The entire process is recorded and traceable, with clear responsibilities that can be held accountable.

04 Full-process aseptic and quality control management

- The key operations are carried out in a highly clean environment and a biosafety cabinet!
- Conduct sterility, endotoxin, mycoplasma, cell viability and phenotypic tests
- Reduce pollution, endotoxin and mycoplasma risks, and ensure the stability of the formulation quality

05 Third-party testing and batch release

- Through the independent testing platform, key indicators such as cell identity, viability, microorganisms, endotoxins and DC maturation degree are verified.
- Data is objective and results can be verified.
- Unqualified products will not be released to ensure safety and controllability

06 Individualized immune closed-loop management

- Combining DC recognition activation, NK rapid clearance, and MSC microenvironment repair
- Form a systematic immune management path of "identification - activation - clearance - maintenance"
- More gentle, more precise, and more suitable for long-term management

Core Summary

The safety of the Thiosys vaccine is achieved through a safety loop constructed by self-source, German GMP standards, German SOP processes, full-process quality control, third-party testing and long-term follow-up.

Please provide a single sentence for translation.

It is not merely a "single injection", but rather the construction of a safer, more controllable and more personalized DC immunization vaccine platform based on German standards.

Safety first
Pre-set control of risk boundaries

Scientific and rigorous
German standard, data-driven

Fully traceable
The records are complete and the responsibilities are clear.

Personalized customization
Dynamic adjustment, precise matching

Long-term follow-up
Continuous monitoring to ensure therapeutic effect

为什么塞奥思体系疫苗更安全？

RARSIG MEDICAL GROUP

不是单一细胞产品，而是一套可追溯、可质控、可复核的个体化免疫平台

01 自体来源 降低免疫风险

- 以患者自身外周血及自体血浆动态抗原信息为基础
- 减少异体来源带来的排斥、免疫识别和外源干扰风险
- 更高生物相容性，更符合个体化免疫管理逻辑

02 德国GMP标准 保障制备可控

- 按照德国/欧盟GMP理念建立制备体系
- 环境、设备、耗材、人员、记录和批次管理全流程受控
- 最大限度降低人为误差、污染风险和批次波动

03 德国SOP流程 确保每一步有标准

- 从采血、样本接收、PBMC分离、DC诱导成熟、质控检测到回输 放行
- 均有标准化操作流程
- 全程记录可追溯，责任清晰可追责

04 全过程无菌与 质控管理

- 关键操作在高洁净环境和生物安全柜内完成
- 进行无菌、内毒素、支原体、细胞活率及表型检测
- 降低污染、内毒素和支原体风险，确保制剂质量稳定

05 第三方检测与 批次放行

- 通过独立检测平台验证细胞身份、活率、微生物、内毒素及DC成熟度等关键指标
- 数据客观、结果可复核
- 不合格不放行，确保安全可控

06 个体化免疫 闭环管理

- 结合DC识别激活、NK快速清除、MSC微环境修复
- 形成“识别—激活—清除—维持”的系统性免疫管理路径
- 更温和、更精准、更适合长期管理

核心总结

塞奥思体系疫苗的安全性，来自自体来源、德国GMP标准、德国SOP流程、全过程质控、第三方检测与长期随访共同构建的安全闭环。

一句话表达

不是简单“打一针”，而是用德国标准构建一套更安全、更可控、更个体化的DC免疫疫苗平台。

安全优先
前置控制风险边界

科学严谨
德国标准，数据驱动

全程可追溯
记录完整，责任明确

个体化定制
动态调整，精准匹配

长期随访
持续监测，保障疗效

推荐使用频率

Recommended Frequency

09

Recommended frequency for the general health and immunity maintenance group (DC-V)

It is recommended to have the test 1 to 4 times a year, and the frequency should be adjusted individually based on age, immune status, lifestyle and test results.

Basic maintenance: once a year

It is suitable for those with stable immune status, regular living habits, and no obvious signs of immune aging. Annual assessment and basic immune maintenance are the main focuses.

Mild fluctuations: twice a year

It is suitable for those who are under high pressure, have irregular sleep patterns, are prone to fatigue or recurrent colds. It can be taken once every six months for phased immune support.

Key maintenance: 3-4 times a year

It is suitable for middle-aged and elderly people, those with a significant tendency towards immune aging, or those at risk of chronic inflammation or in need of long-term postoperative maintenance. It is advisable to arrange it dynamically based on quarterly evaluations.

Dynamic adjustment principle

The frequency of testing should be determined based on the results of immune detection, infection history, recovery status, and the doctor's assessment. It is not recommended to fix the frequency mechanically. Emphasis should be placed on individualized and continuous management.

i 说明: DC-V用于免疫维护与识别支持,具体实施频率应由医生根据评估结果制定;急性感染期或明显炎症活动期不宜实施。

大健康免疫维护人群（DC-V）推荐频率

建议每年 1–4 次，结合年龄、免疫状态、生活方式及检测结果个体化调整

基础维护：每年 1 次

适用于免疫状态稳定、生活规律、无明显免疫衰老迹象者。以年度评估和基础免疫维护为主。

轻度波动：每年 2 次

适用于压力较大、睡眠不规律、易疲劳或反复感冒者。可按半年一次进行阶段性免疫支持。

重点维护：每年 3-4 次

适用于中老年人、免疫衰老倾向明显者，或存在慢性炎症风险、术后长期维护需求者。宜结合季度评估动态安排。

动态调整原则

应结合免疫检测结果、感染史、恢复状态与医生评估，不建议机械固定频率，强调个体化与连续管理。

说明：DC-V用于免疫维护与识别支持，具体实施频率应由医生根据评估结果制定；急性感染期或明显炎症活动期不宜实施。

Recommendation frequency and monitoring principles for cancer patients (DC-T)

It is recommended to conduct this assessment 3-4 times per year, in combination with tumor markers, imaging examinations and immune function evaluations, to develop a dynamic intervention and follow-up strategy.

01

Risk stratification assessment

Based on the type of tumor, stage, treatment stage and risk of recurrence, assess whether it is suitable to undergo DC-T intervention management.

02

Recommended frequency suggestion

The general recommendation is to have 3-4 treatments per year. The specific intervals should be adjusted dynamically based on the stability of the condition and clinical assessment.

03

Timing of reinfusion

It can be carried out during the postoperative recovery period, the interval between radiotherapy and chemotherapy, the maintenance treatment stage, or when monitoring for abnormalities.

04

Multidimensional indicator monitoring

A comprehensive judgment is made by integrating tumor markers, imaging, blood routine, biochemical and immune function indicators.

05

Individualized plan formulation

Develop an individualized plan based on age, nutritional status, coexisting diseases, previous treatment response and tolerance.

06

Efficacy and Response Assessment

Compare the changes in symptoms, laboratory indicators and follow-up results before and after the intervention, and evaluate the effectiveness and safety of the intervention.

07

Integrate prevention and control management

Integrate DC-T into the long-term recurrence monitoring and comprehensive management system, and collaborate with lifestyle and supportive treatment management.

08

Regular clinical follow-up

Establish a continuous follow-up mechanism. If necessary, review the indicators and adjust the frequency to enhance continuity and targeting.

Explanation: DC-T is a therapeutic dendritic cell intervention. The specific implementation frequency and timing should be determined by the clinical doctor based on the patient's condition, infection status, and comprehensive assessment; it is generally not advisable to implement during acute infections or during periods of significant inflammatory activity.

肿瘤患者（DC-T）推荐频率与监测原则

建议每年 3–4 次，结合肿瘤标志物、影像学与免疫功能评估，形成动态干预与随访策略

01

风险分层评估

根据肿瘤类型、分期、治疗阶段及复发风险，评估是否适合进入 DC-T 干预管理。

02

推荐频率建议

一般建议每年 3–4 次，具体间隔应结合病情稳定性与临床评估动态调整。

03

回输时机把握

可结合术后恢复期、放化疗间歇期、维持治疗阶段或监测异常时安排实施。

04

多维指标监测

联合肿瘤标志物、影像学、血常规、生化及免疫功能指标进行综合判断。

05

个体化方案制定

结合年龄、营养状态、合并疾病、既往治疗反应与耐受性制定个体化计划。

06

疗效与反应评估

比较回输前后症状变化、实验室指标及随访结果，评估干预效果与安全性。

07

整合防控管理

将 DC-T 纳入长期复发监测与综合管理体系，协同生活方式与支持治疗管理。

08

定期临床随访

建立持续随访机制，必要时复核指标并调整频率，提升连续性与针对性。

说明：DC-T 属于治疗性树突状细胞干预，具体实施频率与时机应由临床医生根据病情、感染状态及综合评估决定；急性感染或明显炎症活动期一般不宜实施。

DC回输注意事项

Patient Precautions before Injection

10

Key points for assessment and information verification after admission to the hospital

After arriving at the hospital, one should cooperate with the monitoring of vital signs and truthfully provide information about recent medication use, infection history, surgical history, and other important treatment details. This will facilitate the medical staff in conducting safety assessments and arranging procedures.

01

In conjunction with vital sign monitoring

In conjunction with the measurement of basic vital signs such as body temperature, blood pressure, and heart rate, it is used to assess the physical condition of the body on that day, ensuring that related operations are carried out under relatively safe and stable conditions.

02

Verify the recent health status

Please truthfully report whether you have experienced fever, infection, diarrhea or other acute discomfort in the recent period, so that the medical staff can assess whether there are any factors that may affect the safety of the operation.

03

Report your recent medication use truthfully

It is necessary to actively disclose the medications used recently, including antibiotics, hormones, immunosuppressants, anticoagulants and other special medications, so that the medical staff can comprehensively assess the potential effects.

04

Provide information on previous treatments

Please truthfully report the recent and past important treatment details, such as surgeries, chemotherapy, radiotherapy, immunotherapy or other related procedures, to assist the medical staff in assessing the safety and determining the appropriate timing.

到院后评估与信息核查要点

到院后应配合生命体征监测，并如实提供近期用药、感染史、手术史及其他重要治疗信息，便于医护人员开展安全评估与流程安排。

01 配合生命体征监测

配合测量体温、血压、心率等基础生命体征，用于评估当日身体状态，确保相关操作在相对安全、稳定的条件下进行。

02 核实近期健康状况

如实说明近期是否出现发热、感染、腹泻或其他急性不适，以便医护人员评估是否存在影响操作安全性的相关因素。

03 如实报告近期用药

主动说明近期使用的药物，包括抗生素、激素、免疫抑制剂、抗凝药及其他特殊用药，便于医护人员综合判断潜在影响。

04 提供既往治疗信息

如实告知近期及既往重要治疗情况，如手术、化疗、放疗、免疫治疗或其他相关处置，辅助医护人员判断安全性与适宜时机。

Post-DC Reinfusion Precautions

To ensure the quality and safety of the post-reinfusion observation, it is recommended that patients carry out self-management and symptom monitoring under the guidance of medical staff; if any obvious discomfort or abnormal reactions occur, they should promptly contact the medical staff.

01

Moderate rest and hydration

After the infusion, on the same day and the next day, the main focus should be on rest. Maintain a regular diet and drink an appropriate amount of water. Avoid staying up late to help the body maintain a relatively stable state.

02

Prohibition of alcohol, sauna usage, and exposure to high temperatures

Avoid alcohol, saunas, steam baths, prolonged hot water immersion and excessive sun exposure within 24-48 hours after reinfusion to reduce additional physiological burden and vascular dilation stimulation.

03

Avoid strenuous exercise and excessive fatigue

Avoid running within 24 to 48 hours after reinfusion.

Strength training and other high-intensity activities help reduce fatigue load and facilitate the observation of the reaction after reinfusion.

04

Strengthen symptom observation

Pay close attention to changes in body temperature, local redness, swelling, pain, fatigue, diarrhea, and rashes; if the symptoms persist, worsen, or occur anew, please report them in time.

05

Standardized information feedback and medication communication

If you have recently used antibiotics, hormones, immunosuppressants, anticoagulants or other special medications, you should inform the medical staff actively; without assessment, it is not advisable to increase or decrease the dosage of the drugs on your own.

06

Contact medical staff immediately if any abnormalities occur.

If there is persistent fever, obvious rashes, breathing difficulties, chest tightness, persistent diarrhea or any other progressive discomfort, you should contact the medical staff immediately and return for a follow-up visit as required.

The above information serves as general health management guidelines after reinfusion. The specific arrangements will be determined by the clinical doctor's assessment and the institution's procedures.

DC回输后注意事项

为保障回输后观察质量与安全性，建议在医护指导下进行自我管理与症状监测；
如出现明显不适或异常反应，应及时联系医护人员。

01 适度休息与补水

回输后当日及次日以休息为主，保持规律饮食与适量饮水，避免熬夜，帮助机体维持相对稳定状态。

02 禁酒、禁桑拿及高温刺激

回输后24–48小时内避免饮酒、桑拿、蒸浴、长时间热水浸泡及暴晒，以减少额外生理负担和血管扩张刺激。

03 避免剧烈运动与过度劳累

回输后24–48小时内避免跑步、力量训练及其他高强度活动，减少疲劳负荷，便于观察回输后反应。

04 加强症状观察

密切关注体温变化、局部红肿疼痛、乏力、腹泻、皮疹等情况；如症状持续、加重或新发，应及时反馈。

05 规范信息反馈与用药沟通

如近期使用抗生素、激素、免疫抑制剂、抗凝药或其他特殊药物，应主动告知医护人员；未经评估，不宜自行增减药物。

06 出现异常及时联系医护人员

如出现持续发热、明显皮疹、呼吸不适、胸闷、持续腹泻或其他进行性不适，应尽快联系医护人员并按要求复诊。

以上内容用于回输后一般性健康管理提示，具体安排以临床医生评估与机构流程为准。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