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树突状细胞肿瘤疫苗：全球临床试验巡礼 [点此下载全文](#)

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摘要：

自2011年度的诺贝尔生理学或医学奖获得者Ralph M. Steinman发现树突状细胞(dendritic cell, DC)及其在获得性免疫应答中的关键作用以来, 全球范围的DC肿瘤疫苗研究持续进行了数十年, 一系列临床试验正在进行或已经完成, 目前已经有3种DC肿瘤疫苗获得了上市批准: Sipuleucel-T、CreaVax RCC和Hybricell, 但基于DC的免疫治疗方法尚未成为肿瘤治疗的一种标准方法。为了让国内同行深入了解全球范围内开展DC肿瘤疫苗临床试验的现状, 本文基于国际医学期刊编辑委员会认可的临床试验注册网站和PubMed网站数据库对全球DC肿瘤疫苗临床试验概况(地区和国家分布、涉及的肿瘤类型、开展年份和试验分期)作了介绍, 重点对43项已经有论文发表的临床试验情况(受试者选择、DC培养方法、疫苗接种方案、疗效评估方法和试验结果)进行了总结, 着重分析了当前DC肿瘤疫苗临床研究的发展趋势和存在问题, 提出了加强DC肿瘤疫苗临床试验工作的若干建议: 健全我国DC肿瘤疫苗临床试验相关的监管政策; 密切关注国际“体内DC靶向”策略的新动向; 抓紧建立DC培养方法、疫苗接种方案和疗效评估的标准; 加强对DC肿瘤疫苗的质量监控; 重视DC肿瘤疫苗的基础研究和临床试验注册; 提高临床试验方案的质量; 慎重选择受试者和疗效评估时间点; 治疗时应同步开展免疫监测等。抛砖引玉, 以期引起国内同行的重视和讨论, 并尽可能在将来的工作中加以研究和得到解决。

关键词：[树突状细胞](#) [肿瘤疫苗](#) [临床试验](#) [体内DC靶向](#)

Dendritic cell-based cancer vaccines: Current status of global clinical trials [Download Fulltext](#)

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Abstract:

Dendritic cell (DC)-based cancer vaccines have been studied for several decades and a line of clinical trials has been completed or in process since Ralph M. Steinman, a Nobel Prize winner in Physiology or Medicine 2011, found DCs and their crucial role in adaptive immunity. Although three DC-based cancer vaccines (Sipuleucel-T, CreaVax RCC and Hybricell) have been so far approved for marketing, the DC-based immunotherapy has not yet been approved as a standard treatment for cancer. In order to make domestic peers comprehensively understood the current status of global clinical trials of DC vaccines in cancer, the general situation (regional and country distribution, involved cancer type, start year and clinical trial phase) of these clinical trials is introduced and 43 completed and published clinical trials (selecting subject, DC culturing method, vaccination schedule, effectiveness assessment method and trial result) are summarized on the basis of clinical trial registry websites accepted by International Committee of Medical Journal Editors (ICMJE) and PubMed web databases. Then the current development trend and existing problems of clinical trials using DC-based cancer vaccines are emphatically analyzed. Finally, several proposals to improve the clinical studies with DC vaccines against cancer are put forward as follows: perfection and refinement of our regulatory policy on clinical trials of DC-based cancer vaccines; close concern of international “in vivo DC targeting” strategy; grasping to establish DC culturing method, vaccination schedule and effect assessment standard; strengthening quality monitoring of DC-based cancer vaccines; attention to basic research and clinical trial registry of DC-based vaccines for cancer; improving the clinical trial protocols of DC-based cancer vaccines; and careful selection of subjects, effect assessment time points and synchronous application of immune monitoring during cancer treatment. The authors wish to arouse domestic peers' attention and stimulate discussion between them, and these problems will be studied and addressed as possible as we can in the future.

Keywords: [dendritic cell](#) [cancer vaccine](#) [clinical trial](#) [in vivo DC targeting](#)

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