



# 《柳葉刀》雜誌發表中國科學家新冠疫苗I期臨床試驗結果：安全 能誘導免疫反應

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## THE LANCET

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### Safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 vectored COVID-19 vaccine: a dose-escalation, open-label, non-randomised, first-in-human trial

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全球重要醫學學術期刊《柳葉刀》雜誌22日發表了中國21名科學家就新型冠狀病毒疫苗I期試驗結果的論文，結論是：中國團隊研究的全球首個重組腺病毒5型載體新冠疫苗通過安全性測試，並且能夠誘導人體產生免疫反應。

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Safety, tolerability, and immunogenicity of a recombinant ade...

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### Summary

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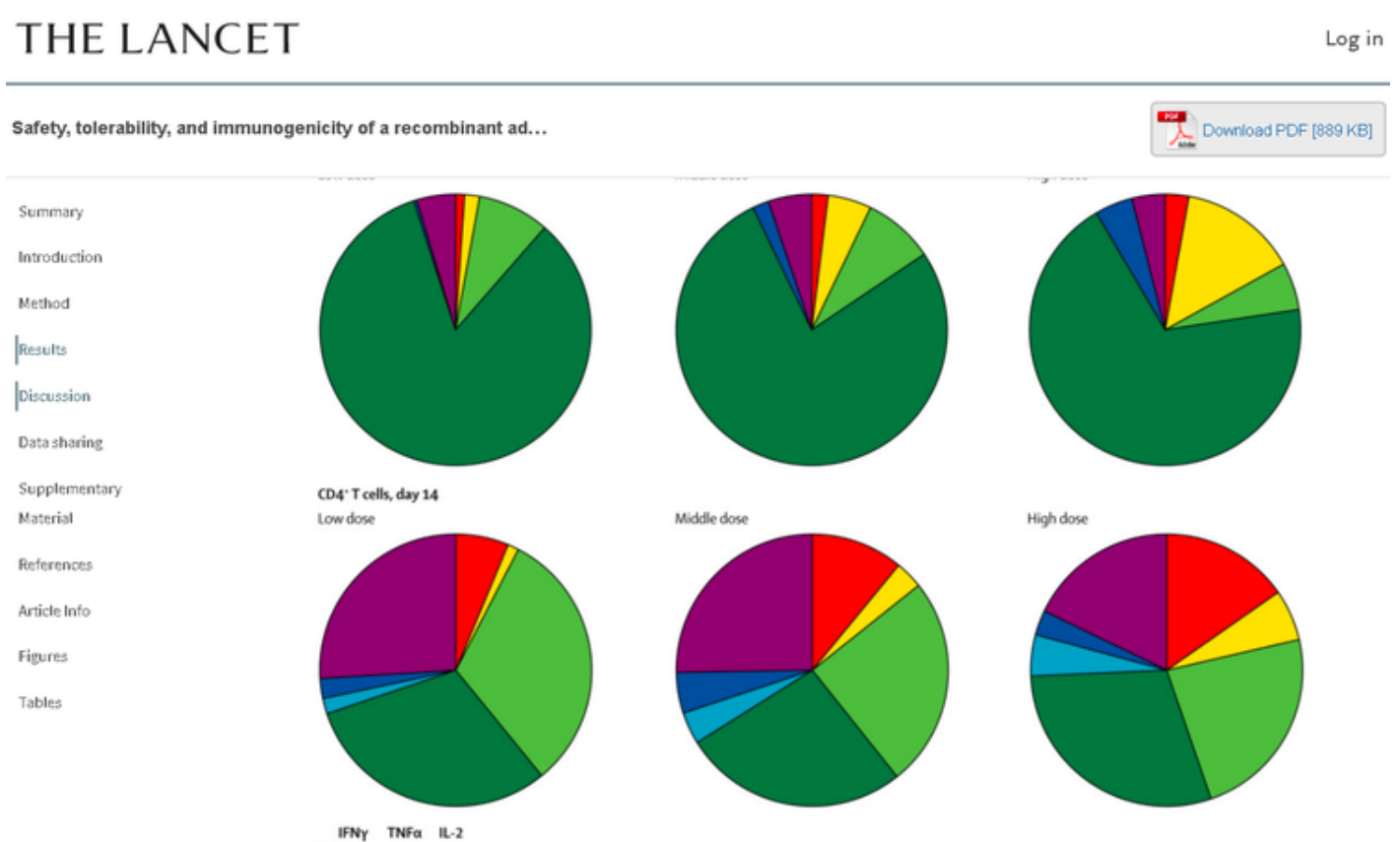
### Findings

Between March 16 and March 27, 2020, we screened 195 individuals for eligibility. Of them, 108 participants (51% male, 49% female; mean age 36·3 years) were recruited and received the low dose (n=36), middle dose (n=36), or high dose (n=36) of the vaccine. All enrolled participants were included in the analysis. At least one adverse reaction within the first 7 days after the vaccination was reported in 30 (83%) participants in the low dose group, 30 (83%) participants in the middle dose group, and 27 (75%) participants in the high dose group. The most common injection site adverse reaction was pain, which was reported in 58 (54%) vaccine recipients, and the most commonly reported systematic adverse reactions were fever (50 [46%]), fatigue (47 [44%]), headache (42 [39%]), and muscle pain (18 [17%]). Most adverse reactions that were reported in all dose groups were mild or moderate in severity. No serious adverse event was noted within 28 days post-vaccination. ELISA antibodies and neutralising antibodies increased significantly at day 14, and peaked 28 days post-vaccination. Specific T-cell response peaked at day 14 post-vaccination.

論文說，在2020年3月16日至3月27日期間，研究團隊篩選了195個人的資格，從中招募了108名參與者（男性51%，女性49%；平均年齡36.3歲），並分成三組每組36人進行了低劑量、中劑量、或高劑量疫苗接種，並將所有登記參與者反應列入分析結果。

試驗中，低劑量組中有30人、中等劑量組30人、高劑量組27人報告了疫苗接種後的前7天內至少有一種不良反應，包括注射部位疼痛、發燒、疲勞、頭痛和肌肉疼痛等；但所有劑量組報告的大多數不良反應為輕度或中度。接種後28天內未發現嚴重不良反應。

在接種後第14天，中和抗體顯著增加，並在接種後28天達到峰值；特異性T細胞反應在接種後第14天達到峰值。



因此，論文結論認為，Ad5載體新冠疫苗在健康成年人中具有耐受性和免疫原性（即，能引起免疫應答）。疫苗接種後第28天，針對SARS-CoV-2的特異性體液

反應達到高峰；注射一劑疫苗後的第14天開始出現快速、特異性的T細胞反應。

研究結果使進一步研究Ad5載體的新冠疫苗、以控制新冠疫情的蔓延成為可能。在中國正在進行的第II期試驗（NCT04341389）將提供有關Ad5載體新冠疫苗的安全性和免疫原性的更多信息。



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The first human trial of a COVID-19 vaccine finds that it is safe, well-tolerated, and induces a rapid immune response. “These results represent an important milestone.” [bit.ly/2WUzNaJ](https://bit.ly/2WUzNaJ)

9:24 pm · 22 May 2020 · [Twitter for iPad](#)

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《柳葉刀》雜誌主編理查德·霍頓通過社交媒體分享了這一進展，稱全球首個對新冠疫苗進行的臨床試驗發現，它是安全的、耐受性良好並能誘導快速的免疫反應。“這些研究結果代表著一個重要的里程碑”。（總臺記者 田曉春）