SARS-CoV-2 Spike Ferritin Nanoparticle Vaccine

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Preclinical Summary

**Cell Reports**

SARS-CoV-2 ferritin nanoparticle vaccines elicit broad SARS coronavirus immunogenicity

**npj | vaccines**

A SARS-CoV-2 spike ferritin nanoparticle vaccine protects hamsters against Alpha and Beta virus variant challenge

**Science Translational Medicine**

**CORONAVIRUS**

A SARS-CoV-2 ferritin nanoparticle vaccine elicits protective immune responses in nonhuman primates

**npj | vaccines**

SARS-CoV-2 ferritin nanoparticle vaccine induces robust innate immune activity driving polyfunctional spike-specific T cell responses

**PNAS**

Efficacy and breadth of adjuvanted SARS-CoV-2 receptor-binding domain nanoparticle vaccine in macaques

Updated 25 February 2022
Design of SARS-CoV-2 Spike Ferritin Nanoparticle (SpFN)
A Suite of Animal Studies:
Consistent Potency & Protection

![Graph showing animal studies and vaccine potencies](Image)
Next Set of Animal Studies

• Multivalent formulations mouse/hamster studies
• Heterologous prime-boost NHP Omicron challenge study
• mRNA formulation mouse studies
• Passive transfer human IgG hamster SARS1/2 challenge
• Adjuvant and Immunogen combination comparison - NHP
Safety and immunogenicity of a ferritin nanoparticle H2 influenza vaccine in healthy adults: a phase 1 trial


https://doi.org/10.1038/s41591-021-01660-8
SpFN Phase I Trial Design

Arm 1
Vaccine: Placebo:: 20: 4

Sentinel group
n=4

Remaining Arm 1 cohort
n=20

n=15
LTFU=0

Greenlight for Arm 2: safety data for n=24

Arm 2
Vaccine: Placebo:: 20: 4

Sentinel group
n=4

25mcg/placebo
50mcg/placebo

Greenlight for Arm 3: safety data for n=24

Age
Arm
0
1
2
3
4

Race/Ethnicity
Multiple
White
Black
Asian

Sex
M
F

18-25 years
26-35 years
36-45 years
46-55 years

24
n=2
LTFU=0
0
29
n=4

29
43
181
29
43
181
29
43
181

SpFN Phase I Trial Flow

Enrollment
- Assessed for Eligibility (n=55)
  - Not Enrolled/Vaccinated (n=26)

Allocation
- Total Enrolled/Vaccinated (n=29)
  - 1st Dose: N=29
  - 2nd Dose: N=28
  - 3rd Dose: N=10

Follow-Up
- Early Termination (n=2)
  - 1 LTFU
  - 1 Moved Away

Analysis
- Primary Immunogenicity and Safety Endpoints Completed (n=28)
SpFN Phase I Trial Endpoints

- Local and Systemic reactogenicity
- Binding antibody (MSD)
- SARS-CoV-2 VOC Pseudovirus Neutralization
- Cell mediated immunity (ICS)
- Sarbecovirus RBD binding antibody (BLI (Octet)) panel
- Broader sarbecovirus neutralization panel
- Purified IgG passive transfer/challenge (Delta, Omicron, SARS1)
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