

# Switzerland - A gold nanoparticle/peptide vaccine designed to induce SARS-CoV-2-specific CD8 T cells: a double-blind, randomized, phase 1 study in Switzerland

**GENTON, Blaise**

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## Identification

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SURVEY ID NUMBER  
10.16909-dataset-54

TITLE  
A gold nanoparticle/peptide vaccine designed to induce SARS-CoV-2-specific CD8 T cells: a double-blind, randomized, phase 1 study in Switzerland

COUNTRY

Name	Country code
Switzerland	CHE

ABSTRACT

**\*\*Background/Objectives\*\***

New vaccines with broader protection against SARS-CoV-2 are needed to reduce the risk of immune escape and provide broad and long-lasting cellular immunity. The objectives of the naNO-COVID trial were to evaluate the safety and immunogenicity of a CD8+ T cell, gold nanoparticle (GNP)-based, peptide COVID-19 vaccine.

**\*\*Methods\*\***

A randomized, double-blind, vehicle-controlled, phase 1 trial in healthy adults to receive PepGNP-Covid19 or Vehicle-GNP, followed over 180 days, using a dose-escalation strategy (ClinicalTrials.gov NCT05113862).

**\*\*Results\*\***

20 participants received PepGNP-Covid19 [low dose (LD) or high dose (HD), n=10 each] and 6 Vehicle-GNP (LD or HD, n=3 each).

Vaccinations were safe. No SAEs were reported. Most of the AEs were mild, two AEs of special interest related to the product (fever and fatigue). Reactogenicity was similar overall between vaccine, comparator, and doses.

Virus-specific humoral responses in LD PepGNP-Covid19 and Vehicle-GNP groups coincided with SARS-CoV-2 infections. PepGNP-Covid19 vaccination induced the modulation of Covid19-specific CD137+CD69+CD8+, and an increase at day 35 particularly in central and effector memory T cells in LD group, and in late effector memory cells in HD group.

**\*\*Conclusions\*\***

The favourable safety profile and cellular responses observed support further development of PepGNP-Covid19.

KIND OF DATA  
Clinical data [cli]

UNIT OF ANALYSIS  
Individuals. 26 participants enrolled.

## Version

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VERSION DATE

## Scope

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KEYWORDS

Keyword
SARS-CoV-2
Nano-Covid
Vaccine
T cell immunity

Nanoparticle-based vaccine

## Producers and sponsors

### PRIMARY INVESTIGATORS

Name	Affiliation
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### PRODUCERS

Name	Affiliation	Role
Juliette Besson	Unisanté, University Center for Primary Care and Public Health	Project coordinator
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Maxime Karlen	Unisanté, University Center for Primary Care and Public Health	Research physician
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Vincent Faivre	Unisanté, University Center for Primary Care and Public Health	Data management
Mohamed Faouzi	Unisanté, University Center for Primary Care and Public Health	Statistician
Mary-Anne Hartley	Unisanté, University Center for Primary Care and Public Health	Co-investigator
François Spertini	CHUV, University Hospital of Lausanne	Immunological evaluator

### FUNDING AGENCY/SPONSOR

Name
Emergex Vaccines Holding Limited

## Data collection

### DATES OF DATA COLLECTION

Start	End
2021.12.03	2022.09.15

### DATA COLLECTION MODE

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## Access policy

### ACCESS CONDITIONS

The dataset can't be share due to ethical restriction. Only the codebook is made available.

### CITATION REQUIREMENTS

BESSION J, AUDRAN R, KARLEN M, MIAUTON A, MABY-EL HAJJAMI H, WARPELIN-DECRAUSAZ L, SENE L, SCHAUFELBERGER S, FAIVRE V, FAOUZI M, HARTLEY MA, SPERTINI F, GENTON B. A gold nanoparticle/peptide vaccine designed to induce SARS-CoV-2-specific CD8 T cells: a double-blind, randomized, phase 1 study in Switzerland. Center for Primary Care and Public

Switzerland - A gold nanoparticle/peptide vaccine designed to induce SARS-CoV-2-specific CD8 T cells: a double-blind, randomized, phase 1 study in Switzerland Health (Unisanté), University of Lausanne, Switzerland. Version 1.0 of the data dictionary, provided by the Unisanté Research Data Repository. DOI:10.16909/DATASET/54

#### ACCESS AUTHORITY

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## Metadata production

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#### PRODUCERS

Name	Abbreviation
Center for Primary Care and Public Health (Unisanté), University of Lausanne, Switzerland	Unisanté

## Data Dictionary

Data file	Cases	Variables
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