Clinical trial results:
P-pVAC-SARS-CoV-2: Phase I single-center safety and immungenicity trial of multi-peptide vaccination to prevent COVID-19 infection in adults

Summary

EudraCT number	2020-002502-75
Trial protocol	DE
Global end of trial date	21 September 2021

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	P-pVAC-SARS-CoV-2

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University Hospital Tuebingen
Sponsor organisation address	Otfried-Mueller-Strasse 10, Tuebingen, Germany, 72076
Public contact	Zentrum für Klinische Studien, University Hospital Tuebingen, 49 70712985638, zks-pm@med.uni-tuebingen.de
Scientific contact	Zentrum für Klinische Studien, University Hospital Tuebingen, 49 70712985638, zks-pm@med.uni-tuebingen.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	21 September 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 September 2021
Global end of trial reached?	Yes
Global end of trial date	21 September 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and immunogenicity of a single use of a SARS-CoV-2 specific multi-peptide vaccine in combination with the TLR1/2 ligand XS15 in adults

The primary objective of this trial is to evaluate the safety and tolerability of the CoVac-1 vaccine, a single dose SARS-CoV-2 specific multi-peptide vaccine combined with the TLR1/2 ligand XS15 emulsified in Montanide ISA 51 VG in adults.

Protection of trial subjects:

The procedures set out in this trial protocol, pertaining to the conduct, evaluation, and documentation of this trial, are designed to ensure that all persons involved in the trial act according to Good Clinical Practice (GCP) and the ethical principles described in the applicable version of the Declaration of Helsinki.

Each volunteer will be informed about the modalities of the clinical study in accordance with the provided volunteer informed consent (IC). The volunteer is to be informed both in writing and verbally by the investigator before any study-specific procedure is performed. The volunteer must be given sufficient time to decide whether to participate in this comparative study and to ask questions concerning this trial. It must also be made clear to the volunteer that he / she can withdraw from the study at any time without giving reasons and that he / she will not be in any way disadvantaged for this. The subject must give consent in writing. The volunteer and informing physician must each personally date and sign the informed consent form with an integrated declaration on data privacy protection, whereby the physician must not sign before the volunteer. Original signed documents will be part of the investigator’s file and retained with it. A copy of the signed informed consent document and study insurance policy must be given to the subject. The documents must be in a language understandable to the subject and must specify who informed the subject. The subjects will be informed as soon as possible if new information may influence his/her decision to participate in the trial. The communication of this information should be documented in the volunteer chart.

Each volunteer is insured against any health impairment occurring as a result of participation in the study in accordance with the laws and regulations of the “German Arzneimittelgesetz”.

Travel insurance will be included for all volunteers enrolled in the clinical trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 November 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 36

Worldwide total number of subjects	36
EEA total number of subjects	36

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	12
From 65 to 84 years	24
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

From November 28th 2020 to January 15th 2021, 12 healthy adults were enrolled in part I (age group 18–55 years). From March 24th 2021 to April 1st 2021, 24 adults were enrolled in part II (age group 56–80 years). All the recruitment process was conducted in University Hospital Tuebingen (Germany).

Pre-assignment

Screening details:

The study population were healthy subjects (volunteers): Healthy adult women and men aged 18-55 (Part I), followed by adult women and men aged 56-80 with age adjusted health condition (Part II). The trial population consisted of both genders.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

This clinical study is a phase I, single-center, non- randomized, single-arm, uncontrolled and open-label trial.

Arms

Arm title	Investigational arm

Arm description:

The trial is a single-arm design where all subjects received the CoVac-1 vaccine (investigational medicinal product).

Arm type	Experimental
Investigational medicinal product name	CoVac-1: Peptide cocktail emulsified in Montanide ISA 51 VG
Investigational medicinal product code	
Other name	CoVac-1
Pharmaceutical forms	Emulsion for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

A single vaccination with the IMP CoVac-1 (SARS-CoV-2 HLA-DR peptides, XS15 emulsified in Montanide ISA 51 VG) (500 µl) will be applied subcutaneously (s.c.) to the abdominal skin.

Number of subjects in period 1	Investigational arm
Started	36
Completed	36

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	36	36	
Age categorical Units: Subjects			
Adults (18-64 years)	12	12	
From 65-84 years	24	24	
Age continuous			
From 24 March 2021 to 1 April 2021, 24 adults were enrolled in part II (age group 56–80 years). Of part I and part II participants, 33% and 50%, respectively, were female participants. The median participant age was 38 (range 23–50) and 62 (range 56–70) years for part I and part II, respectively.			
Units: years			
median	50		
full range (min-max)	23 to 70	-	
Gender categorical Units: Subjects			
Female	16	16	
Male	20	20	

End points

End points reporting groups

Reporting group title	Investigational arm

Reporting group description:

The trial is a single-arm design where all subjects received the CoVac-1 vaccine (investigational medicinal product).

Primary: Safety and Tolerability

End point title	Safety and Tolerability[1]

End point description:

The primary endpoint was the nature, frequency, and severity of AEs and/or SAEs associated with administration of CoVac-1.

Solicited: ADRs/AE occurring from the time of each injection throughout 28 days following the procedure, facilitated by use of a volunteer diary:
-Unsolicited: AEs from the time of injection throughout 56 days following injection.
-SAEs from the time of injection until the final study visit for each.
-Incidence of AESIs until the final study visit for each subject.

End point type	Primary

End point timeframe:

Until day 56 since the vaccine administration

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical details and charts can be found in the scientific publication:

https://www.nature.com/articles/s41586-021-04232-5#citeas

https://pubmed.ncbi.nlm.nih.gov/34814158/

End point values	Investigational arm			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Adverse Events	36			

Statistical analyses

No statistical analyses for this end point

Secondary: Imnunogenicity

End point title	Imnunogenicity

End point description:

T cell responses were assessed in all participants at baseline (day 1), on days 7, 14 and 28, as well as in the follow-up period on day 56 and month 3 after vaccination.

End point type	Secondary

End point timeframe:

T cell responses were assessed in all participants at baseline (day 1), on days 7, 14 and 28, as well as in the follow-up period on day 56 and month 3 after vaccination.

End point values	Investigational arm			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: CD4+ and CD8+ T cell responses	36			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Primary safety outcomes reflect the nature, frequency and severity of solicited adverse events until day 56 after vaccination.

Adverse event reporting additional description:

The documentation was facilitated by use of a volunteer diary (for 28 days after vaccination) and graded by the investigators according to a modified Common Terminology Criteria for Adverse Events (CTCAE) V5.0 grading scale

Assessment type	Systematic

Dictionary used

Dictionary name	CTCAE
Dictionary version	5

Reporting groups

Reporting group title	Investigational arm

Reporting group description:

The trial is a single-arm design where all subjects received the CoVac-1 vaccine (investigational medicinal product).

Serious adverse events	Investigational arm		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 36 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Investigational arm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	36 / 36 (100.00%)		
General disorders and administration site conditions			
Local granuloma	Additional description: Local granuloma in the vaccination site		
subjects affected / exposed	36 / 36 (100.00%)		
occurrences (all)	36		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported