Clinical trial results:
A clinical study of biomarkers of innate and adaptive immune activation associated with symptoms and immune responses after administration of a single dose of a quadrivalent inactivated split virus influenza vaccine to healthy young adults.

Summary

EudraCT number	2017-000116-42
Trial protocol	BE
Global end of trial date	17 May 2017

Results information

Result version number	v1 (current)
This version publication date	08 September 2024
First version publication date	08 September 2024
Summary attachment (see zip file)	Protocol (2017-000116-42-Protocol.pdf)

Trial information

Trial identification

Sponsor protocol code	BioVacSafe-QIV

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	Corneel Heymanslaan 10, Ghent, Belgium, 9000
Public contact	Hiruz CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be
Scientific contact	Hiruz CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be

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	17 May 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 May 2017
Global end of trial reached?	Yes
Global end of trial date	17 May 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this protocol is to generate a set of data that will be analysed by integrated systems biology approach, for validation in subsequent clinical trials or in animal models. The dataset will broadly characterise: :
1. Physiological responses at various time points after immunisation
2. Innate and adaptive immune responses
3. Genetic testing of subjects when deemed necessary (genetic testing analysis may be SNIP analysis or full genome analysis).
4. Correlations in changes in innate and adaptive immune activation with adverse events, haematology and biochemistry panels, genotype and physiological assessments

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 March 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

20 patients were screened in the period from 27-03-2017 till 18-04-2017. 20 patients were included. 20 patients were included and completed the trial. End of trial notification was dated 17-05-2017 (last patient last visit) and submitted to EC and CA 8/09/2017.

Pre-assignment

Screening details:

Inclusion criteria:
- Healthy male/female subjects: 24-54 years inclusive.
- BMI ≥18 and ≤30
- signed the ICF
- available for follow-up
- agrees to abstain from donating blood during participation
- heterosexually active female, willing to use contraception
- willing to undergo urine pregnancy test
- sufficient venous access

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Baseline arm
Arm description: -	
Arm type	Baseline arm
No investigational medicinal product assigned in this arm	
Arm title	Treatment arm
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	a-RIX-Tetra
Investigational medicinal product code	
Other name	Alfa-Rix Tetra 2016-2017
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

A quadrivalent inactivated split virus influenza vaccine for the 2016/2017 season.
1 dose, 0.5 mL, to be administered on Day 0, the first visit.

Number of subjects in period 1	Baseline arm	Treatment arm
Started	20	20
Completed	20	20

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	20	20	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	20	20	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	0	0	
Male	20	20	

End points

End points reporting groups

Reporting group title	Baseline arm
Reporting group description: -	
Reporting group title	Treatment arm
Reporting group description: -	

Primary: Variable end points

End point title	Variable end points[1]
End point description:	
See protocol in attachment	
End point type	Primary
End point timeframe:	
Overall Study	

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: NAP

End point values	Baseline arm	Treatment arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: Subjects				
number (not applicable)	20	20		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Overall Study	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.1

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: NAP

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