Clinical trial results:
A clinical study to generate a set of data characterising clinical events, physiological responses, and innate and adaptive immune responses following a single intramuscular immunisation with FluadTM seasonal influenza vaccine or saline as placebo control in healthy adults.

Summary

EudraCT number	2014-003543-35
Trial protocol	BE
Global end of trial date	16 December 2014

Results information

Result version number	v1 (current)
This version publication date	01 December 2024
First version publication date	01 December 2024
Summary attachment (see zip file)	Last Patient Last Visit (notifictie LVLP.pdf)

Trial information

Trial identification

Sponsor protocol code	BioVacSafe–FluadTM

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University Hospital Ghent
Sponsor organisation address	C. Heymanslaan, Ghent, Belgium, 9000
Public contact	Bimetra Clinics, Ghent University Hospital, +32 93320500, bimetra.clinics@uzgent.be
Scientific contact	Bimetra Clinics, Ghent University Hospital, +32 93320500, bimetra.clinics@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	16 December 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 December 2014
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. Metabolic, 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 and metabolism with adverse events, haematology and biochemistry panels, genotype and physiological assessments

We will biobank all samples for the duration of the BIOVACSAFE programme so that we can selectively analyse different samples and different time points depending on the results generated, principally from the gene expression analysis of whole blood.

Protection of trial subjects:

See Protocol

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 October 2014
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: 240
Worldwide total number of subjects	240
EEA total number of subjects	240

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	240
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Via CEVAC database and website

Pre-assignment

Screening details:

NAP

Period 1

Period 1 title	Overal Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Blinding implementation details:

Observer-blind (subject, investigator and laboratory blinded), randomised, placebo controlled exploratory “confirmatory study”.

Arms

Are arms mutually exclusive?	Yes
Arm title	GROUP A

Arm description:

- FluadTM, seasonal trivalent inactivated influenza vaccine for season 2014-2015 (Northern hemisphere)
- Single 0.5 mL dose
- Intramuscular
- One injection on one occasion
- 228 subjects

Arm type	Active comparator
Investigational medicinal product name	Fluad TM
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

- FluadTM, seasonal trivalent inactivated influenza vaccine for season 2014-2015 (Northern hemisphere)
- Single 0.5 mL dose
- Intramuscular
- One injection on one occasion

Arm title	GROUP B

Arm description:

- GROUP B
- Saline placebo 0.5 mL
- Intramuscular
- One injection on one occasion
- 12 subjects

Arm type	Placebo

Investigational medicinal product name	Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

- Saline placebo 0.5 mL
- Intramuscular
- One injection on one occasion

Number of subjects in period 1	GROUP A	GROUP B
Started	228	12
Completed	228	12

Baseline characteristics

End points

End points reporting groups

Reporting group title	GROUP A

Reporting group description:

- FluadTM, seasonal trivalent inactivated influenza vaccine for season 2014-2015 (Northern hemisphere)
- Single 0.5 mL dose
- Intramuscular
- One injection on one occasion
- 228 subjects

Reporting group title	GROUP B

Reporting group description:

- GROUP B
- Saline placebo 0.5 mL
- Intramuscular
- One injection on one occasion
- 12 subjects

Primary: Primary

End point title	Primary[1]

End point description:

1. Frequency of local and systemic vaccine-related clinical events at all time points from vaccination up to last study visit.
2. Change from pre-immunisation baseline values in pulse, temperature, blood pressure at all time points from time of immunisation up to last study visit.
3. Change from pre-immunisation baseline values in haematology (blood counts and ESR), biochemistry (liver, renal and bone panels) parameters at selected time points from time of immunisation up to last study visit.
4. Change from pre-immunisation baseline values in global gene expression measured on whole blood samples at selected time points from time of immunisation up to last study visit
5. Change from pre-immunisation baseline values and fold increase in serum HAI titre in serum samples at selected time points from time of immunisation up to last study visit.

End point type	Primary

End point timeframe:

During the 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	GROUP A	GROUP B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	228	12		
Units: values				
number (not applicable)	228	12		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
During the study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

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: See attachment

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