



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 FludaxTM 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 (notificatie LVLP.pdf) |

Trial information

Trial identification

| | |
|-----------------------|---------------------------------|
| Sponsor protocol code | BioVacSafe-Fludax TM |
|-----------------------|---------------------------------|

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 | Overall 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:

- FludTM, 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 | Flud TM |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for solution for injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

- FludTM, 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: | |
| <ul style="list-style-type: none">• FludTM, 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: | |
| <ul style="list-style-type: none">• 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: | |
| <ol style="list-style-type: none">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 visit5. 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