



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