



Clinical trial results:

Corifollitropin alfa followed by hp-HMG versus recombinant FSH in young poor ovarian responders. A multicentre randomized controlled clinical trial

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2013-000583-29 |
| Trial protocol | BE |
| Global end of trial date | 31 May 2016 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 02 July 2022 |
| First version publication date | 02 July 2022 |

Trial information

Trial identification

| | |
|-----------------------|--------------|
| Sponsor protocol code | 143201316398 |
|-----------------------|--------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01816321 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Universitair Ziekenhuis Brussel |
| Sponsor organisation address | Laarbeeklaan 101, Brussel, Belgium, 1090 |
| Public contact | Nikolaos Polyzos, Universitair Ziekenhuis Brussel, 0032 24776699, nikolaos.polyzos@uzbrussel.be |
| Scientific contact | Nikolaos Polyzos, Universitair Ziekenhuis Brussel, 0032 24776699, nikolaos.polyzos@uzbrussel.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 | 30 December 2016 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 31 May 2016 |
| Global end of trial reached? | Yes |
| Global end of trial date | 31 May 2016 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To compare pregnancy rates after treatment with corifollitropin alfa followed by highly purified HMG versus recombinant FSH in a GnRH antagonist protocol, for the treatment of young poor ovarian responders undergoing ovarian stimulation for ICSI

Protection of trial subjects:

Treated in Routine care

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 15 March 2013 |
| 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: 88 |
| Country: Number of subjects enrolled | Viet Nam: 64 |
| Worldwide total number of subjects | 152 |
| EEA total number of subjects | 88 |

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) | 152 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Enrolment was performed from March 2013 to May 2016.

Pre-assignment

Screening details:

Eligible Patient are screened in period March 2013- May 2016 ,

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | overall trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Blinding implementation details:

No blinding

Arms

| | |
|------------------------------|--|
| Are arms mutually exclusive? | Yes |
| Arm title | COrifollitropin alfa followed by Menotropin for Poor Ovarian R |

Arm description:

Patients will be randomised to either corifollitropin alfa followed by hpHMG (Group A) or to rFSH (Group B)

| | |
|--|----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | corifollitropin alfa |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

150 µg corifollitropin alfa ,subcutaneous

| | |
|------------------|------|
| Arm title | rFSH |
|------------------|------|

Arm description:

Reference group: a daily SC dose of rFSH (300 IU/day)

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | rFSH |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

300IU daily

| Number of subjects in period 1 | CORefolliotropin alfa followed by Menotropin for Poor Ovarian R | rFSH |
|--------------------------------|--|------|
| | | |
| Started | 77 | 75 |
| Completed | 77 | 75 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|---------------|
| Reporting group title | overall trial |
|-----------------------|---------------|

Reporting group description: -

| Reporting group values | overall trial | Total | |
|--|---------------|-------|--|
| Number of subjects | 152 | 152 | |
| Age categorical | | | |
| age defined by inclusion criteria : less than 40 years | | | |
| 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) | 152 | 152 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| 18-40 years | 0 | 0 | |
| Age continuous | | | |
| Units: years | | | |
| log mean | 0 | | |
| standard deviation | ± 0 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 152 | 152 | |
| Male | 0 | 0 | |

End points

End points reporting groups

| | |
|---|--|
| Reporting group title | CORifollitropin alfa followed by Menotropin for Poor Ovarian R |
| Reporting group description: | |
| Patients will be randomised to either corifollitropin alfa followed by hpHMG (Group A) or to rFSH (Group B) | |
| Reporting group title | rFSH |
| Reporting group description: | |
| Reference group: a daily SC dose of rFSH (300 IU/day) | |

Primary: ongoing pregnancy rates

| | |
|--|-------------------------|
| End point title | ongoing pregnancy rates |
| End point description: | |
| The primary efficacy endpoint is the ongoing pregnancy rates, defined as the presence of intrauterine gestational sac with an embryonic pole demonstrating cardiac activity at 9-10 weeks of gestation. The primary efficacy endpoint is related to the primary trial objective. | |
| End point type | Primary |
| End point timeframe: | |
| cardiac activity at 9-10 weeks of gestation | |

| End point values | CORifollitropin alfa followed by Menotropin for Poor Ovarian R | rFSH | | |
|-----------------------------|--|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 77 | 75 | | |
| Units: 22 | | | | |
| number (not applicable) | 77 | 75 | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Statistical Analysis |
| Comparison groups | CORifollitropin alfa followed by Menotropin for Poor Ovarian R v rFSH |
| Number of subjects included in analysis | 152 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | ≤ 0.05 |
| Method | Wilcoxon (Mann-Whitney) |
| Parameter estimate | Mean difference (final values) |

| | |
|----------------------|--------------------|
| Confidence interval | |
| level | Other: 85 % |
| sides | 2-sided |
| Variability estimate | Standard deviation |

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

March 2013- May 2016

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

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|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 16.0 |
|--------------------|------|

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: There are no Adverse events reported

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|--|
| 30 November 2015 | Amendment 1, protocol vs 2 , 2 Nov 2015 : Department of Obstetrics and Gynaecology, University of Medicine and Pharmacy HCMC, Ho Chi Minh City, Vietnam is added as 2nd recruiting site in this trial |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

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|----|
| no |
|----|

Notes: