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 treament 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 alfafollowed 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	COrifollitropin alfafollowed 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 alfafollowed 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 alfafollowed 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 alfafollowed 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	
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.

no

Notes: