Clinical trial results:
Comparative study between the usage of corifollitropin alfa and daily recombinant FSH in the ovarian stimulation of low responders

Summary

EudraCT number	2013-002979-17
Trial protocol	ES
Global end of trial date	16 November 2015

Results information

Result version number	v1 (current)
This version publication date	30 October 2020
First version publication date	30 October 2020

Trial information

Trial identification

Sponsor protocol code	1309-SEV-130-MF

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	IVI Sevilla
Sponsor organisation address	Avenida República Argentina 58 Sevilla, Sevilla, Spain,
Public contact	Research associate, IVI Sevilla, +34 954286274, victor.blasco@ivi.es
Scientific contact	Research associate, IVI Sevilla, +34 954286274, victor.blasco@ivi.es

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 November 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 November 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect on the number of mature oocytes obtained after the follicular puncture depending on the stimulation protocol applied:
-Stimulation protocol A (experimental): controlled ovarian stimulation using corifollitropin alfa
-Stimulation protocol B (control): controlled ovarian stimulation using recombinant FSH and highly purified HMG

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 September 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	Spain: 26
Worldwide total number of subjects	26
EEA total number of subjects	26

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)	26
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients will be recruited for a year (from November 2013 to November 2014).

Pre-assignment

Screening details:

They must go through at least two stimulation cycles.
-They are low responders to ovarian stimulation according to the Bologna criteria.
-They accept voluntarily to participate in the trial signing an informed consent form.
According to the Bologna criteria, at least two of the following three features must be present to be considered low r

Pre-assignment period milestones

Number of subjects started	26
Number of subjects completed	11

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Physician decision: 15

Period 1

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

Arms

Arm title	Elonva

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Elonva
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

150 µg microgram

Number of subjects in period 1[1]	Elonva
Started	11
Completed	11

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Premature cancellation

Baseline characteristics

End points

End points reporting groups

Reporting group title	Elonva

Reporting group description: -

Primary: Number of mature oocytes obtained after the follicular puncture

End point title	Number of mature oocytes obtained after the follicular puncture[1]

End point description:

End point type	Primary

End point timeframe:

1 year

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: Premature cancellation. Results have not been analysed

End point values	Elonva			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: %				

Notes:

[2] - Premature cancellation

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 3 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 1 %

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: Phase IV study with a low level of intervention. No adverse events were detected

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? Yes

Date	Interruption	Restart date
16 November 2015	No funding	-

Notes:

Limitations and caveats

None reported