Clinical trial results:
Prospective, open-label, uncontrolled clinical trial evaluating multiple controlled ovarian hyperstimulation cycles in oocyte donor, to assess the immunogenicity of FSH-IBSA

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2012-000269-19
Trial protocol	ES
Global end of trial date	16 July 2014
Results information	
Result version number	v2 (current)
This version publication date	24 February 2016
First version publication date	25 December 2014
Version creation reason	• Correction of full data set corrections due to software errors
Summary attachment (see zip file)	Synopsis (11E-FSH03-Clinical report-final-17Nov2014-Synopsis.pdf)

Trial information

Trial identification	
Sponsor protocol code	11E/FSH03
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01785095
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	IBSA Institut Biochimique SA
Sponsor organisation address	via del Piano, Pambio Noranco, Switzerland,
Public contact	Senior Clinical Research Manager, IBSA Institute Biochimique SA, +41 583601000, barbara.cometti@ibsa.ch
Scientific contact	Senior Clinical Research Manager, IBSA Institut Biochimique SA, +41 583601000, barbara.cometti@ibsa.ch

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 November 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 July 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the study is to evaluate immunogenic potential of FSH-IBSA in healthy volunteers undergoing COH in an oocyte donation program.

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 May 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: 41
Worldwide total number of subjects	41
EEA total number of subjects	41

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)	41
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Inclusion Criteria
Healthy female volunteers undergoing controlled ovarian hyperstimulation for oocyte donation.

Period 1

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

Arms

Arm title	Urofollitrophin

Arm description:

FSH-IBSA (IBSA, Institut Biochimique SA), powder and solvent for solution for s.c. injection, supplied in vials containing 75 IU of FSH, along with prefilled syringes of solvent (physiological saline for injection)

Arm type	Experimental
Investigational medicinal product name	FSH-IBSA
Investigational medicinal product code	
Other name	Urofollitrophin
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were instructed on FSH-IBSA self-administration and supplied with medication, with the first dose being administered by the Investigator or his/her delegate. Dosage from a minimum of75 IU and a maximum of450 IU according to subjects response.

Number of subjects in period 1	Urofollitrophin
Started	41
Included	27
Completed	24
Not completed	17
Consent withdrawn by subject	1
Adverse event, non-fatal	1
screening failure	14
treatment cancellation	1

Baseline characteristics

Reporting groups

Reporting group title	Urofollitrophin

Reporting group description:

FSH-IBSA (IBSA, Institut Biochimique SA), powder and solvent for solution for s.c. injection, supplied in vials containing 75 IU of FSH, along with prefilled syringes of solvent (physiological saline for injection)

Reporting group values	Urofollitrophin	Total	
Number of subjects	41	41	
Age categorical			
Fertile, premenopausal women			
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)	41	41	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Fertile, premenopausal women.			
Units: Subjects			
Female	41	41	
Male	0	0	

Subject analysis sets

Subject analysis set title	All randomised subjects
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All randomised patients

Reporting group values	All randomised subjects		
Number of subjects	27		
Age categorical			
Fertile, premenopausal women			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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) From 65-84 years 85 years and over	27 0 0		
Gender categorical			
Fertile, premenopausal women.			
Units: Subjects			
Female Male	27		

End points

End points reporting groups

Reporting group title	Urofollitrophin

Reporting group description:

FSH-IBSA (IBSA, Institut Biochimique SA), powder and solvent for solution for s.c. injection, supplied in vials containing 75 IU of FSH, along with prefilled syringes of solvent (physiological saline for injection)

Subject analysis set title	All randomised subjects
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All randomised patients

Primary: anti-FSH antibodies

End point title	anti-FSH antibodies[1]

End point description:

To test the production of anti-FSH antibodies (IgG, IgM, and IgA) using a sensitive screening assay.

End point type	Primary

End point timeframe:

At day 1, after 6-8 days, after 28 days.

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: No statistical analysis was planned since the end point was to assess the production of antibodies against FSH. No antibodies were detected. No statistical analysis was performed.

End point values	Urofollitrophin	All randomised subjects		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	27	27		
Units: presence or absence				
number (not applicable)	27	27		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Throughout the study period.	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	17
Reporting groups	
Reporting group title	Randomised subjects
Reporting group description: All the subjects who were randomised and had at least one FSH injection.	

Serious adverse events	Randomised subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 27 (3.70%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Randomised subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 27 (25.93%)		
Injury, poisoning and procedural complications			
lymb injury			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Nervous system disorders			
Dizziness			

subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	3 / 27 (11.11%)		
occurrences (all)	3		
General disorders and administration site conditions			
pirexia			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Musles spasm			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Infections and infestations			
bacteria vaginosis			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
candida infection			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		

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