



Clinical trial results:

An AMH based individualised controlled ovarian stimulation regimen using

Corifollitrophin or graded doses of rFSH versus a standard protocol. A randomised controlled trial

Summary

EudraCT number	2012-004969-40
Trial protocol	DK
Global end of trial date	10 January 2017

Results information

Result version number	v1 (current)
This version publication date	17 September 2021
First version publication date	17 September 2021

Trial information

Trial identification

Sponsor protocol code	RHFERAMH-0001
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Blegdamsvej, Copenhagen, Denmark, 2100
Public contact	Professor Anders Nyboe Andersen, Fertility Clinic, Copenhagen University Hospital, Rigshospitalet, +45 35451315, anders.nyboe.andersen@regionh.dk
Scientific contact	Professor Anders Nyboe Andersen, Fertility Clinic, Copenhagen University Hospital, Rigshospitalet, +45 35451315, anders.nyboe.andersen@regionh.dk

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	05 September 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 November 2016
Global end of trial reached?	Yes
Global end of trial date	10 January 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To show that the group randomized to individual AMH based stimulation achieves a more homogeneous distribution of the retrieved eggs than the group receiving standard treatment.

Primary endpoint:

The primary endpoint is an appropriate or an inappropriate number of oocytes:

This should be understood in the term of patients in the two arms are classified as having an appropriate response (5 - 14 eggs) or inappropriate response (<5 or > 14 eggs);

An inappropriate response includes those patients where the treatment is canceled due to either too few follicles or egg maturation with hCG omitted due to risk of OHSS (given as GnRH agonist (Suprefact) instead of)

Protection of trial subjects:

None besides regular good clinical practice

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 January 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	Denmark: 221
Worldwide total number of subjects	221
EEA total number of subjects	221

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)	221
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Clinical interview

Period 1

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

Arms

Are arms mutually exclusive? Yes

Arm title Intervention

Arm description:

Individualized FSH dosing

Arm type Individualized dosing

Investigational medicinal product name Puregon

Investigational medicinal product code

Other name

Pharmaceutical forms Concentrate for suspension for injection

Routes of administration Injection

Dosage and administration details:

As usually adm. inf fertility treatment

Arm title Standard dosing

Arm description:

Standard FSH dosing

Arm type Normal dosing

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Intervention	Standard dosing
Started	149	72
Completed	149	72

Baseline characteristics

End points

End points reporting groups

Reporting group title	Intervention
Reporting group description:	
Individualized FSH dosing	
Reporting group title	Standard dosing
Reporting group description:	
Standard FSH dosing	

Primary: Intended number of oocytes retrieved

End point title	Intended number of oocytes retrieved
End point description:	
End point type	Primary
End point timeframe:	
November 2017	

End point values	Intervention	Standard dosing		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	149	72		
Units: Patients	105	55		

Statistical analyses

Statistical analysis title	Proportion of patients to reach intended target
Comparison groups	Standard dosing v Intervention
Number of subjects included in analysis	221
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	< 0.05
Method	Chi-squared

Notes:

[1] - basic calculations

Adverse events

Adverse events information

Timeframe for reporting adverse events:

February 2013 to November 2018

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	unknown
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Reporting groups

Reporting group title	Minor
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Reporting group description: -

Serious adverse events	Minor		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 221 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 4 %

Non-serious adverse events	Minor		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 221 (0.45%)		
Skin and subcutaneous tissue disorders			
Discomfort from injection			
subjects affected / exposed	1 / 221 (0.45%)		
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