Clinical trial results:
A randomised, double-blind, placebo-controlled, parallel-group, dose-range trial to investigate the efficacy and safety of FE 999302 as add-on treatment to follitropin delta (REKOVELLE) in women undergoing controlled ovarian stimulation in a long GnRH agonist protocol

Summary

EudraCT number	2017-003810-13
Trial protocol	CZ DK BE GB ES
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	07 January 2021
First version publication date	07 January 2021

Trial information

Trial identification

Sponsor protocol code	000289

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03564509
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ferring Pharmaceuticals A/S
Sponsor organisation address	International PharmaScience Center, Kay Fiskers Plads 11, Copenhagen S, Denmark, 2300
Public contact	Global Clinical Compliance, Ferring Pharmaceuticals, DK0-Disclosure@ferring.com
Scientific contact	Global Clinical Compliance, Ferring Pharmaceuticals, DK0-Disclosure@ferring.com

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	Interim
Date of interim/final analysis	30 January 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 October 2019
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the effects of FE 999302 on parameters influencing pregnancy rates in women undergoing Controlled Ovarian Stimulation (COS) with follitropin delta in a long gonadotropin releasing hormone (GnRH) agonist protocol.

Protection of trial subjects:

The trial was performed in accordance with the version of Declaration of Helsinki in force at the initiation of the trial. The trial was performed in compliance with International Council for Harmonisation Good Clinical Practice (ICH GCP).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 May 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 60
Country: Number of subjects enrolled	Spain: 297
Country: Number of subjects enrolled	Belgium: 34
Country: Number of subjects enrolled	Czechia: 170
Country: Number of subjects enrolled	Denmark: 59
Worldwide total number of subjects	620
EEA total number of subjects	620

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)	620
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The trial was performed in 5 countries, and a total of 20 sites randomised subjects to the trial (2 in Belgium, 4 in Czech Republic, 4 in Denmark, 6 in Spain, and 4 in United Kingdom) between May 2018 to Jan 2020.

Pre-assignment

Screening details:

In total, 773 subjects were screened of which 620 subjects were randomised. Of the randomised subjects, 619 subjects were exposed to investigational medicinal product (IMP): 515 to FE 999302 and 104 to placebo. The number of subjects exposed to each of the dose levels were: 104, 101, 99, 107, and 104 to 1, 2, 4, 8, and 12 µg, respectively.

Period 1

Period 1 title	Randomised Treatment Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

FE 999302 and placebo were identical in appearance and the trial was considered double-blind as neither the subject nor the investigator knew whether the subject was receiving FE 999302 or placebo.

Arms

Are arms mutually exclusive?	Yes
Arm title	FE 999302 (1 µg) and Follitropin Delta

Arm description:

Dose 1 µg of FE 999302, a recombinant human choriogonadotropin (rhCG) solution for subcutaneous injection; individualised follitropin delta dose

Arm type	Experimental and add-on treatment
Investigational medicinal product name	FE 999302 (1 µg)
Investigational medicinal product code	FE 999302
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dose 1 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

Arm title	FE 999302 (2 µg) and Follitropin Delta

Arm description:

Dose 2 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

Arm type	Experimental and add-on treatment
Investigational medicinal product name	FE 999302 (2 µg)
Investigational medicinal product code	FE 999302
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dose 2 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

Arm title	FE 999302 (4 µg) and Follitropin Delta

Arm description:

Dose 4 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

Arm type	Experimental and add-on treatment
Investigational medicinal product name	FE 999302 (4 µg)
Investigational medicinal product code	FE 999302
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dose 4 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

Arm title	FE 999302 (8 µg) and Follitropin Delta

Arm description:

Dose 8 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

Arm type	Experimental and add-on treatment
Investigational medicinal product name	FE 999302 (8 µg)
Investigational medicinal product code	FE 999302
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dose 8 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

Arm title	FE 999302 (12 µg) and Follitropin Delta

Arm description:

Dose 12 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

Arm type	Experimental and add-on treatment
Investigational medicinal product name	FE 999302 (12 µg)
Investigational medicinal product code	FE 999302
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dose 12 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose

Arm title	Placebo and Follitropin Delta

Arm description:

Placebo and individualised follitropin delta dose

Arm type	Placebo and add-on treatment
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo and individualised follitropin delta dose

Number of subjects in period 1[1]	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta
Started	104	101	99
Completed	101	99	94
Not completed	3	2	5
Consent withdrawn by subject	-	1	1
Adverse event, non-fatal	1	1	3
Other	1	-	1
Lost to follow-up	1	-	-

Number of subjects in period 1[1]	FE 999302 (8 µg) and Follitropin Delta	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta
Started	107	104	104
Completed	99	100	98
Not completed	8	4	6
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	7	4	5
Other	-	-	-
Lost to follow-up	1	-	1

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: In total, 773 subjects were screened. Of these, 153 were screening failures and 620 were randomised. Of the 620 randomised subjects, 619 subjects were exposed to IMP. The subject that was not exposed to IMP fulfilled exclusion criterion 6 (abnormal karyotype) and should not have been randomised.

Baseline characteristics

Reporting groups	
Reporting group title	FE 999302 (1 µg) and Follitropin Delta
Reporting group description:	
Dose 1 µg of FE 999302, a recombinant human choriogonadotropin (rhCG) solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	FE 999302 (2 µg) and Follitropin Delta
Reporting group description:	
Dose 2 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	FE 999302 (4 µg) and Follitropin Delta
Reporting group description:	
Dose 4 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	FE 999302 (8 µg) and Follitropin Delta
Reporting group description:	
Dose 8 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	FE 999302 (12 µg) and Follitropin Delta
Reporting group description:	
Dose 12 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	Placebo and Follitropin Delta
Reporting group description:	
Placebo and individualised follitropin delta dose	

Reporting group values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta
Number of subjects	104	101	99
Age categorical Units: Subjects			
30-37 years	73	71	68
38-42 years	31	30	31
Age continuous Units: years			
arithmetic mean	35.6	35.6	35.5
standard deviation	± 3.3	± 3.4	± 3.2
Gender categorical Units: Subjects			
Female	104	101	99
Male	0	0	0
Race Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	2	2	3
Black or African American	0	2	0
Multiple	0	0	0
White	101	97	96
Ethnicity Units: Subjects			
Hispanic or Latino	2	5	1
Not Hispanic or Latino	102	96	98

Body mass index (BMI)			
Units: kg/m^2			
arithmetic mean	24.1	23.6	23.7
standard deviation	± 3.5	± 3.3	± 3.7

Reporting group values	FE 999302 (8 µg) and Follitropin Delta	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta
Number of subjects	107	104	104
Age categorical			
Units: Subjects			
30-37 years	71	71	72
38-42 years	36	33	32
Age continuous			
Units: years			
arithmetic mean	35.7	35.3	35.6
standard deviation	± 3.5	± 3.5	± 3.2
Gender categorical			
Units: Subjects			
Female	107	104	104
Male	0	0	0
Race			
Units: Subjects			
American Indian or Alaska Native	0	0	2
Asian	2	2	2
Black or African American	0	2	0
Multiple	1	0	0
White	104	100	100
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	1	2
Not Hispanic or Latino	107	103	102
Body mass index (BMI)			
Units: kg/m^2			
arithmetic mean	24.5	24.2	23.6
standard deviation	± 3.8	± 3.8	± 3.1

Reporting group values	Total		
Number of subjects	619		
Age categorical			
Units: Subjects			
30-37 years	426		
38-42 years	193		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	619		
Male	0		

Race Units: Subjects			
American Indian or Alaska Native	3		
Asian	13		
Black or African American	4		
Multiple	1		
White	598		
Ethnicity Units: Subjects			
Hispanic or Latino	11		
Not Hispanic or Latino	608		
Body mass index (BMI) Units: kg/m^2			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

Reporting group title	FE 999302 (1 µg) and Follitropin Delta
Reporting group description:	
Dose 1 µg of FE 999302, a recombinant human choriogonadotropin (rhCG) solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	FE 999302 (2 µg) and Follitropin Delta
Reporting group description:	
Dose 2 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	FE 999302 (4 µg) and Follitropin Delta
Reporting group description:	
Dose 4 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	FE 999302 (8 µg) and Follitropin Delta
Reporting group description:	
Dose 8 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	FE 999302 (12 µg) and Follitropin Delta
Reporting group description:	
Dose 12 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	Placebo and Follitropin Delta
Reporting group description:	
Placebo and individualised follitropin delta dose	

Primary: Number of good-quality blastocysts on day 5 after oocyte retrieval (grade 3BB or higher)

End point title	Number of good-quality blastocysts on day 5 after oocyte retrieval (grade 3BB or higher)
End point description:	
Quality of blastocysts was assessed by blastocyst expansion and hatching status, blastocyst inner cell mass grading, and trophectoderm grading. The scoring was based on the classification system by Gardner and Schoolcraft, with additional categories for inner cell mass (degenerative or no inner cell mass) and trophectoderm (degenerative or very large cells). The analysis population included the full analysis set (FAS) which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.	
End point type	Primary
End point timeframe:	
On day 5 after oocyte retrieval	

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: Number of blastocysts				
arithmetic mean (standard deviation)	2.3 (± 2.1)	3.0 (± 2.8)	2.3 (± 2.5)	2.6 (± 2.5)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: Number of blastocysts				
arithmetic mean (standard deviation)	2.2 (± 2.4)	3.3 (± 2.9)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	= 0.0012
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	0.85

Notes:

[1] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and anti-Müllerian hormone (AMH) group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[2]
P-value	= 0.3822
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.15

Notes:

[2] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[3]
P-value	= 0.0021
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	0.86

Notes:

[3] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[4]
P-value	= 0.0491
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	1

Notes:

[4] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[5]
P-value	= 0.0005
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.63

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	0.82

Notes:

[5] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Secondary: Number and quality of embryos on day 3 after oocyte retrieval

End point title	Number and quality of embryos on day 3 after oocyte retrieval

End point description:

Number of embryos (total and good-quality) on Day 3. A good-quality embryo was defined as an embryo with ≥6 cells and ≤25% fragmentation, or with embryo stage classified as compacting/compacted.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

On day 3 after oocyte retrieval

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: Number of embryos				
arithmetic mean (standard deviation)				
Number of embryos	6.1 (± 3.6)	6.2 (± 3.9)	5.7 (± 3.7)	6.0 (± 3.6)
Number of good-quality embryos	4.9 (± 3.2)	5.2 (± 3.5)	4.4 (± 3.3)	4.9 (± 3.1)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: Number of embryos				
arithmetic mean (standard deviation)				
Number of embryos	5.2 (± 3.7)	7.4 (± 4.2)		
Number of good-quality embryos	4.3 (± 3.5)	6.0 (± 3.7)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo
Statistical analysis description:	
Treatment comparison: Number of embryos	
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[6]
P-value	= 0.007
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	0.94

Notes:

[6] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Statistical analysis description:	
Treatment comparison: Number of embryos	
Comparison groups	Placebo and Follitropin Delta v FE 999302 (2 µg) and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[7]
P-value	= 0.0183
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	0.97

Notes:

[7] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Statistical analysis description:	
Treatment comparison: Number of embryos	
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[8]
P-value	= 0.0005
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.88

Notes:

[8] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo

Statistical analysis description:

Treatment comparison: Number of embryos

Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[9]
P-value	= 0.0069
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	0.94

Notes:

[9] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo

Statistical analysis description:

Treatment comparison: Number of embryos

Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[10]
P-value	< 0.0001
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.69

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.81

Notes:

[10] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo

Statistical analysis description:

Treatment comparison: Number of good-quality embryos

Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[11]
P-value	= 0.0055
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.93

Notes:

[11] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo

Statistical analysis description:

Treatment comparison: Number of good-quality embryos

Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[12]
P-value	= 0.0593
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.01

Notes:

[12] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo

Statistical analysis description:	
Treatment comparison: Number of good-quality embryos	
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[13]
P-value	= 0.0002
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	0.85

Notes:

[13] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Statistical analysis description:	
Treatment comparison: Number of good-quality embryos	
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[14]
P-value	= 0.0096
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	0.94

Notes:

[14] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Statistical analysis description:	
Treatment comparison: Number of good-quality embryos	
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[15]
P-value	< 0.0001
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.68

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.82

Notes:

[15] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Secondary: Number and quality of blastocysts on day 5 after oocyte retrieval

End point title	Number and quality of blastocysts on day 5 after oocyte retrieval

End point description:

Number of blastocysts (total and good-quality) on Day 5. Blastocyst quality was assessed by blastocyst expansion and hatching status, blastocyst inner cell mass grading, and trophectoderm grading. The scoring was based on the classification system by Gardner and Schoolcraft, with additional categories for inner cell mass (degenerative or no inner cell mass) and trophectoderm (degenerative or very large cells).

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

On day 5 after oocyte retrieval

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: Number of blastocysts				
arithmetic mean (standard deviation)	4.1 (± 3.0)	4.7 (± 3.5)	3.8 (± 3.0)	4.3 (± 3.4)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: Number of blastocysts				
arithmetic mean (standard deviation)	3.6 (± 3.3)	5.3 (± 3.8)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[16]
P-value	= 0.0068
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	0.92

Notes:

[16] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[17]
P-value	= 0.1553
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.06

Notes:

[17] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[18]
P-value	= 0.0005
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	0.85

Notes:

[18] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[19]
P-value	= 0.0235
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.97

Notes:

[19] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[20]
P-value	< 0.0001
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	0.81

Notes:

[20] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Secondary: Changes in serum hormone (progesterone) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval

End point title	Changes in serum hormone (progesterone) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, end-of-stimulation, and at oocyte retrieval.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12

µg), Placebo
Stimulation day 6: n=104, n=99, n=97, n=105, n=104, n=103
Stimulation day 8: n=102, n=97, n=95, n=103, n=100, n=100
End-of-stimulation: n=104, n=99, n=99, n=104, n=103, n=102
Oocyte retrieval: n=103, n=100, n=98, n=106, n=102, n=101

End point type	Secondary

End point timeframe:

Stimulation Day 1 (baseline), Stimulation Day 6, stimulation Day 8, end-of-stimulation (up to 20 stimulation days), and oocyte retrieval

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: nmol/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	0.094 (± 0.486)	0.050 (± 0.320)	0.306 (± 2.454)	0.187 (± 0.361)
Stimulation Day 8	0.599 (± 2.887)	0.317 (± 0.407)	0.377 (± 0.562)	0.620 (± 0.702)
End-of-stimulation visit	1.327 (± 1.001)	1.429 (± 0.984)	1.687 (± 1.636)	2.407 (± 1.608)
Oocyte retrieval visit	28.304 (± 16.381)	26.426 (± 15.671)	23.680 (± 16.108)	23.666 (± 12.553)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: nmol/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	0.268 (± 0.450)	-0.215 (± 2.691)		
Stimulation Day 8	0.691 (± 0.638)	0.022 (± 2.734)		
End-of-stimulation visit	2.555 (± 1.571)	1.090 (± 2.797)		
Oocyte retrieval visit	21.818 (± 10.590)	31.154 (± 16.586)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[21]
P-value	= 0.4287
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.3

Notes:

[21] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[22]
P-value	= 0.4301
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.3

Notes:

[22] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[23]
P-value	= 0.1019
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.41

Notes:

[23] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[24]
P-value	= 0.0046
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.09
upper limit	1.57

Notes:

[24] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[25]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.28
upper limit	1.85

Notes:

[25] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[26]
P-value	= 0.8375
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.02

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.25

Notes:

[26] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[27]
P-value	= 0.9139
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.24

Notes:

[27] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[28]
P-value	= 0.2647
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.38

Notes:

[28] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[29]
P-value	= 0.0007
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.16
upper limit	1.74

Notes:

[29] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[30]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	1.95

Notes:

[30] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[31]
P-value	= 0.8069
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.16

Notes:

[31] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[32]
P-value	= 0.4818
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.26

Notes:

[32] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[33]
P-value	= 0.0754
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.39

Notes:

[33] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[34]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.65

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.39
upper limit	1.96

Notes:

[34] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[35]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.54
upper limit	2.16

Notes:

[35] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[36]
P-value	= 0.0885
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.02

Notes:

[36] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[37]
P-value	= 0.0146
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	0.96

Notes:

[37] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[38]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.84

Notes:

[38] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[39]
P-value	= 0.0006
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.88

Notes:

[39] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[40]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.84

Notes:

[40] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation day 1 as a covariate.

Secondary: Changes in serum hormone (17-OH-progesterone) levels of from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval

End point title	Changes in serum hormone (17-OH-progesterone) levels of from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, end-of-stimulation, and at oocyte retrieval.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo
Stimulation day 6: n=103, n=99, n=97, n=105, n=104, n=102
Stimulation day 8: n=101, n=97, n=96, n=102, n=101, n=100
End-of-stimulation: n=102, n=99, n=99, n=104, n=104, n=101
Oocyte retrieval: n=102, n=99, n=98, n=106, n=103, n=98

End point type	Secondary

End point timeframe:

Stimulation Day 1 (baseline), stimulation Day 6, stimulation Day 8, end-of-stimulation (up to 20 stimulation days), and oocyte retrieval

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: nmol/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	0.716 (± 0.612)	0.855 (± 1.052)	1.121 (± 0.835)	1.622 (± 1.251)
Stimulation Day 8	1.542 (± 1.132)	2.026 (± 1.443)	2.594 (± 1.973)	3.701 (± 2.739)
End-of-stimulation visit	4.840 (± 2.934)	5.559 (± 3.362)	7.025 (± 5.274)	10.022 (± 6.007)
Oocyte retrieval visit	22.518 (± 10.417)	24.565 (± 12.943)	25.505 (± 14.471)	42.227 (± 144.990)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: nmol/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	1.940 (± 1.428)	0.335 (± 0.585)		
Stimulation Day 8	4.123 (± 2.716)	1.076 (± 1.161)		
End-of-stimulation visit	10.605 (± 5.849)	3.635 (± 2.425)		
Oocyte retrieval visit	27.218 (± 13.283)	18.278 (± 8.826)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[41]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.25
upper limit	1.64

Notes:

[41] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[42]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.46
upper limit	1.93

Notes:

[42] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[43]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	2.12

Notes:

[43] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[44]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.45

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.14
upper limit	2.81

Notes:

[44] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[45]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.37
upper limit	3.11

Notes:

[45] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[46]
P-value	= 0.0008
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.12
upper limit	1.52

Notes:

[46] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[47]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.36
upper limit	1.86

Notes:

[47] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[48]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.58
upper limit	2.16

Notes:

[48] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[49]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.2
upper limit	2.99

Notes:

[49] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[50]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.41
upper limit	3.28

Notes:

[50] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[51]
P-value	= 0.0025
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.09
upper limit	1.47

Notes:

[51] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[52]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.48

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.27
upper limit	1.72

Notes:

[52] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[53]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.5
upper limit	2.04

Notes:

[53] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[54]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.19
upper limit	2.96

Notes:

[54] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[55]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.32
upper limit	3.14

Notes:

[55] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[56]
P-value	= 0.0198
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.03
upper limit	1.37

Notes:

[56] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[57]
P-value	= 0.0003
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	1.51

Notes:

[57] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[58]
P-value	= 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.15
upper limit	1.54

Notes:

[58] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[59]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.37
upper limit	1.83

Notes:

[59] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[60]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.48

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.28
upper limit	1.71

Notes:

[60] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Secondary: Changes in serum hormone (androstenedione) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval

End point title	Changes in serum hormone (androstenedione) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, end-of-stimulation, and at oocyte retrieval.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo
Stimulation day 6: n=104, n=100, n=97, n=105, n=103, n=103
Stimulation day 8: n=102, n=97, n=95, n=103, n=100, n=101
End-of-stimulation: n=104, n=99, n=99, n=104, n=103, n=102
Oocyte retrieval: n=103, n=100, n=98, n=106, n=102, n=101

End point type	Secondary

End point timeframe:

Stimulation Day 1 (baseline), stimulation Day 6, stimulation Day 8, end-of-stimulation (up to 20 stimulation days), and oocyte retrieval

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: nmol/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	0.91 (± 0.97)	1.26 (± 1.23)	1.29 (± 1.21)	1.86 (± 1.48)
Stimulation Day 8	2.02 (± 1.44)	2.77 (± 2.12)	3.19 (± 2.12)	4.44 (± 3.09)
End-of-stimulation visit	5.48 (± 2.97)	6.37 (± 3.73)	7.64 (± 4.64)	9.99 (± 5.39)
Oocyte retrieval visit	6.50 (± 3.49)	7.17 (± 4.01)	8.58 (± 3.88)	10.76 (± 5.48)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: nmol/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	2.17 (± 1.60)	0.35 (± 0.95)		
Stimulation Day 8	4.65 (± 2.82)	1.22 (± 1.51)		
End-of-stimulation visit	9.66 (± 5.01)	3.03 (± 2.13)		
Oocyte retrieval visit	10.34 (± 5.10)	4.06 (± 2.54)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[61]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.09
upper limit	1.28

Notes:

[61] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[62]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.19
upper limit	1.4

Notes:

[62] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin

	Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[63]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.21
upper limit	1.43

Notes:

[63] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[64]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.39
upper limit	1.63

Notes:

[64] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[65]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.47
upper limit	1.72

Notes:

[65] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[66]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	1.35

Notes:

[66] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[67]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.25
upper limit	1.52

Notes:

[67] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[68]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.51

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.37
upper limit	1.67

Notes:

[68] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[69]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.67
upper limit	2.02

Notes:

[69] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[70]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.7
upper limit	2.06

Notes:

[70] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[71]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.27
upper limit	1.56

Notes:

[71] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[72]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.41
upper limit	1.74

Notes:

[72] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[73]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	1.98

Notes:

[73] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[74]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	2.45

Notes:

[74] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[75]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.96
upper limit	2.41

Notes:

[75] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[76]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.34

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.21
upper limit	1.48

Notes:

[76] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[77]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.31
upper limit	1.59

Notes:

[77] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[78]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.53
upper limit	1.87

Notes:

[78] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[79]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.81
upper limit	2.2

Notes:

[79] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[80]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.75
upper limit	2.14

Notes:

[80] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Secondary: Changes in serum hormone (testosterone) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval

End point title	Changes in serum hormone (testosterone) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, end-of-stimulation, and at oocyte retrieval.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo
Stimulation day 6: n=101, n=98, n=97, n=105, n=103, n=102
Stimulation day 8: n=100, n=96, n=95, n=103, n=100, n=100
End-of-stimulation: n=101, n=98, n=99, n=104, n=103, n=100
Oocyte retrieval: n=101, n=98, n=98, n=106, n=103, n=100

End point type	Secondary

End point timeframe:

Stimulation Day 1 (baseline), stimulation Day 6, stimulation Day 8, end-of-stimulation (up to 20

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: nmol/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	0.152 (± 0.201)	0.190 (± 0.252)	0.224 (± 0.226)	0.319 (± 0.317)
Stimulation Day 8	0.382 (± 0.299)	0.414 (± 0.396)	0.604 (± 0.467)	0.824 (± 0.616)
End-of-stimulation visit	1.178 (± 0.736)	1.252 (± 0.786)	1.605 (± 1.097)	2.296 (± 1.380)
Oocyte retrieval visit	2.088 (± 1.105)	2.213 (± 1.198)	2.691 (± 1.321)	3.394 (± 1.780)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: nmol/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	0.371 (± 0.335)	0.039 (± 0.187)		
Stimulation Day 8	0.847 (± 0.575)	0.195 (± 0.277)		
End-of-stimulation visit	2.106 (± 1.165)	0.669 (± 0.472)		
Oocyte retrieval visit	3.136 (± 1.586)	1.374 (± 0.798)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[81]
P-value	= 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.18

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	1.31

Notes:

[81] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[82]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.14
upper limit	1.39

Notes:

[82] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[83]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.23
upper limit	1.5

Notes:

[83] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[84]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.39
upper limit	1.69

Notes:

[84] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[85]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.46
upper limit	1.79

Notes:

[85] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[86]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.14
upper limit	1.43

Notes:

[86] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[87]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.16
upper limit	1.46

Notes:

[87] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[88]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.42
upper limit	1.79

Notes:

[88] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[89]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.91

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.71
upper limit	2.14

Notes:

[89] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[90]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.74
upper limit	2.17

Notes:

[90] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[91]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.25
upper limit	1.6

Notes:

[91] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[92]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.31
upper limit	1.67

Notes:

[92] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[93]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.56
upper limit	1.99

Notes:

[93] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[94]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.1
upper limit	2.68

Notes:

[94] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[95]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.99
upper limit	2.54

Notes:

[95] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[96]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.21
upper limit	1.52

Notes:

[96] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[97]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.45

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.29
upper limit	1.62

Notes:

[97] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[98]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.53
upper limit	1.92

Notes:

[98] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[99]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.87
upper limit	2.33

Notes:

[99] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[100]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.75
upper limit	2.19

Notes:

[100] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Secondary: Changes in serum hormone (estradiol) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval

End point title	Changes in serum hormone (estradiol) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, end-of-stimulation, and oocyte retrieval

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, end-of-stimulation, and at oocyte retrieval.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo
Stimulation day 6: n=101, n=96, n=96, n=101, n=101, n=101
Stimulation day 8: n=99, n=93, n=94, n=99, n=100, n=100
End-of-stimulation: n=102, n=93, n=97, n=99, n=100, n=101
Oocyte retrieval: n=100, n=94, n=94, n=98, n=98, n=99

End point type	Secondary

End point timeframe:

Stimulation Day 1 (baseline), stimulation Day 6, stimulation Day 8, end-of-stimulation (up to 20 stimulation days), and oocyte retrieval

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: pmol/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	1183.4 (± 813.0)	1413.4 (± 1028.7)	1412.5 (± 1154.1)	1612.9 (± 1098.4)
Stimulation Day 8	2994.9 (± 1692.1)	3526.3 (± 2186.1)	3707.9 (± 3100.8)	4204.8 (± 2478.1)
End-of-stimulation visit	9119.7 (± 4984.4)	10006.3 (± 5322.4)	10640.9 (± 6305.4)	12705.8 (± 7412.0)
Oocyte retrieval visit	4410.7 (± 2308.4)	4781.2 (± 2299.5)	5925.5 (± 4389.5)	7672.5 (± 10951.6)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: pmol/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	1619.1 (± 1242.4)	880.7 (± 959.2)		
Stimulation Day 8	3969.7 (± 2364.1)	2257.9 (± 1704.3)		
End-of-stimulation visit	11098.9 (± 5905.2)	6864.6 (± 3706.8)		
Oocyte retrieval visit	6502.4 (± 2957.4)	3273.2 (± 1729.9)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[101]
P-value	= 0.0095
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	1.61

Notes:

[101] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[102]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.57

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.27
upper limit	1.93

Notes:

[102] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[103]
P-value	= 0.0002
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	1.82

Notes:

[103] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[104]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.51
upper limit	2.27

Notes:

[104] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[105]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.37
upper limit	2.07

Notes:

[105] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[106]
P-value	= 0.0016
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	1.67

Notes:

[106] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[107]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.34
upper limit	1.99

Notes:

[107] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	Placebo and Follitropin Delta v FE 999302 (4 µg) and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[108]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.34
upper limit	2

Notes:

[108] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[109]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.59
upper limit	2.35

Notes:

[109] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[110]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.48
upper limit	2.18

Notes:

[110] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[111]
P-value	= 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.15
upper limit	1.52

Notes:

[111] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	Placebo and Follitropin Delta v FE 999302 (2 µg) and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[112]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.27
upper limit	1.7

Notes:

[112] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[113]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.34
upper limit	1.78

Notes:

[113] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	Placebo and Follitropin Delta v FE 999302 (8 µg) and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[114]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.62
upper limit	2.16

Notes:

[114] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[115]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.42
upper limit	1.89

Notes:

[115] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[116]
P-value	= 0.0004
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	1.55

Notes:

[116] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[117]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.25
upper limit	1.72

Notes:

[117] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[118]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.66

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.41
upper limit	1.94

Notes:

[118] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[119]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.84
upper limit	2.52

Notes:

[119] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Oocyte retrieval)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[120]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	2.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.73
upper limit	2.36

Notes:

[120] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Secondary: Changes in serum hormone (inhibin A) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation

End point title	Changes in serum hormone (inhibin A) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation

End point description:

Blood samples for analysis serum hormone levels were drawn at stimulation Day 1, stimulation Day 6,

stimulation Day 8, and at end-of-stimulation.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo
Stimulation day 6: n=94, n=94, n=94, n=100, n=100, n=90
Stimulation day 8: n=94, n=94, n=93, n=97, n=93, n=89
End-of-stimulation: n=95, n=95, n=93, n=99, n=101, n=89

End point type	Secondary

End point timeframe:

Stimulation Day 1 (baseline), Stimulation Day 6, stimulation Day 8, and end-of-stimulation (up to 20 stimulation days)

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: ng/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	57.0 (± 43.7)	62.1 (± 42.8)	56.9 (± 40.2)	61.0 (± 45.9)
Stimulation Day 8	145.7 (± 88.3)	151.6 (± 88.4)	140.7 (± 80.0)	155.1 (± 101.1)
End-of-stimulation visit	380.1 (± 148.5)	367.3 (± 158.1)	356.4 (± 153.6)	368.2 (± 179.5)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: ng/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	61.7 (± 47.2)	58.1 (± 42.2)		
Stimulation Day 8	149.4 (± 92.8)	148.2 (± 90.0)		
End-of-stimulation visit	319.1 (± 148.9)	398.0 (± 165.7)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[121]
P-value	= 0.7029
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.18

Notes:

[121] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[122]
P-value	= 0.4906
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.33

Notes:

[122] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[123]
P-value	= 0.8638
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.26

Notes:

[123] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[124]
P-value	= 0.4434
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.33

Notes:

[124] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[125]
P-value	= 0.9426
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.22

Notes:

[125] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[126]
P-value	= 0.5904
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.95

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.14

Notes:

[126] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[127]
P-value	= 0.5444
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.27

Notes:

[127] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[128]
P-value	= 0.9847
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.21

Notes:

[128] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[129]
P-value	= 0.4027
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.3

Notes:

[129] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[130]
P-value	= 0.8388
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.18

Notes:

[130] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[131]
P-value	= 0.3474
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.07

Notes:

[131] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[132]
P-value	= 0.1652
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.04

Notes:

[132] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[133]
P-value	= 0.1168
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.03

Notes:

[133] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[134]
P-value	= 0.1567
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.92

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.03

Notes:

[134] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[135]
P-value	= 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	0.89

Notes:

[135] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Secondary: Changes in serum hormone (inhibin B) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation

End point title	Changes in serum hormone (inhibin B) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, and at end-of-stimulation.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo
Stimulation day 6: n=99, n=97, n=95, n=103, n=103, n=96
Stimulation day 8: n=98, n=95, n=93, n=101, n=98, n=94
End-of-stimulation: n=97, n=94, n=94, n=102, n=103, n=94

End point type	Secondary

End point timeframe:

Stimulation Day 1 (baseline), Stimulation Day 6, stimulation Day 8, and end-of-stimulation (up to 20 stimulation days)

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: ng/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	527.4 (± 256.8)	538.2 (± 283.7)	475.2 (± 258.1)	505.3 (± 255.8)
Stimulation Day 8	735.1 (± 271.2)	684.9 (± 274.5)	650.7 (± 256.8)	652.5 (± 261.9)
End-of-stimulation visit	731.7 (± 285.8)	668.7 (± 275.4)	662.0 (± 268.5)	620.5 (± 264.5)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: ng/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	456.0 (± 269.2)	535.4 (± 275.8)		
Stimulation Day 8	569.1 (± 261.6)	717.7 (± 291.7)		
End-of-stimulation visit	531.5 (± 264.9)	742.0 (± 287.2)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[136]
P-value	= 0.8145
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.21

Notes:

[136] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[137]
P-value	= 0.8796
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.2

Notes:

[137] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[138]
P-value	= 0.1413
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.04

Notes:

[138] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[139]
P-value	= 0.898
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.17

Notes:

[139] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[140]
P-value	= 0.02
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	0.97

Notes:

[140] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[141]
P-value	= 0.7899
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.17

Notes:

[141] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[142]
P-value	= 0.4413
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.95

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.09

Notes:

[142] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[143]
P-value	= 0.1804
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.04

Notes:

[143] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[144]
P-value	= 0.2936
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.06

Notes:

[144] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[145]
P-value	= 0.0002
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	0.88

Notes:

[145] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[146]
P-value	= 0.5204
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.09

Notes:

[146] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[147]
P-value	= 0.0468
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1

Notes:

[147] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[148]
P-value	= 0.0417
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	0.99

Notes:

[148] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[149]
P-value	= 0.0084
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.96

Notes:

[149] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[150]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.69

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.78

Notes:

[150] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Secondary: Changes in serum hormone (follicle stimulating hormone [FSH]) levels of from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation

End point title	Changes in serum hormone (follicle stimulating hormone [FSH]) levels of from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation

End point description:

Blood samples for analysis of serum hormone levels were drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, at end-of-stimulation.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12 µg), Placebo
Stimulation day 6: n=103, n=101, n=94, n=104, n=104, n=101
Stimulation day 8: n=99, n=96, n=93, n=103, n=101, n=99
End-of-stimulation: n=102, n=99, n=97, n=103, n=102, n=101

End point type	Secondary

End point timeframe:

Stimulation Day 1 (baseline), stimulation Day 6, stimulation Day 8, and end-of-stimulation (up to 20 stimulation days)

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: IU/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	10.77 (± 3.39)	11.57 (± 3.51)	11.44 (± 3.85)	10.95 (± 3.20)
Stimulation Day 8	11.16 (± 3.48)	12.19 (± 4.02)	12.12 (± 4.22)	11.56 (± 3.58)
End-of-stimulation visit	11.11 (± 3.54)	12.20 (± 4.31)	11.87 (± 3.91)	11.67 (± 3.73)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: IU/L				
arithmetic mean (standard deviation)				

Stimulation Day 6	11.08 (± 3.72)	11.03 (± 3.55)		
Stimulation Day 8	11.93 (± 4.20)	11.60 (± 3.50)		
End-of-stimulation visit	11.92 (± 4.41)	11.73 (± 3.87)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[151]
P-value	= 0.8378
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.05

Notes:

[151] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[152]
P-value	= 0.2155
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.09

Notes:

[152] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[153]
P-value	= 0.5823
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.07

Notes:

[153] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[154]
P-value	= 0.9766
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.05

Notes:

[154] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[155]
P-value	= 0.7826
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.06

Notes:

[155] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[156]
P-value	= 0.5283
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.04

Notes:

[156] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[157]
P-value	= 0.2565
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.1

Notes:

[157] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[158]
P-value	= 0.671
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.07

Notes:

[158] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[159]
P-value	= 0.9139
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.06

Notes:

[159] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[160]
P-value	= 0.3999
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.09

Notes:

[160] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[161]
P-value	= 0.4039
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.03

Notes:

[161] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[162]
P-value	= 0.5442
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.08

Notes:

[162] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[163]
P-value	= 0.7983
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.05

Notes:

[163] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[164]
P-value	= 0.8476
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.05

Notes:

[164] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[165]
P-value	= 0.6936
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.07

Notes:

[165] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Secondary: Changes in serum hormone (luteinising hormone [LH]) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation

End point title	Changes in serum hormone (luteinising hormone [LH]) levels from stimulation Day 1 to stimulation Day 6, stimulation Day 8, and end-of-stimulation

End point description:

Blood samples for analysis of hormone concentrations are drawn at stimulation Day 1, stimulation Day 6, stimulation Day 8, and at end-of-stimulation.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

Timeframe: FE 999302 (1 µg), FE 999302 (2 µg), FE 999302 (4 µg), FE 999302 (8 µg), FE 999302 (12

µg), Placebo
Stimulation day 6: n=103, n=101, n=97, n=104, n=104, n=102
Stimulation day 8: n=100, n=97, n=95, n=103, n=101, n=100
End-of-stimulation: n=103, n=99, n=99, n=103, n=102, n=101

End point type	Secondary

End point timeframe:

Stimulation Day 1 (baseline), stimulation Day 6, stimulation Day 8, and end-of-stimulation (up to 20 stimulation days)

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: IU/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	-0.75 (± 0.72)	-0.79 (± 0.86)	-0.66 (± 0.75)	-0.76 (± 0.88)
Stimulation Day 8	-0.70 (± 0.83)	-0.78 (± 0.99)	-0.67 (± 0.93)	-0.64 (± 1.04)
End-of-stimulation visit	-0.56 (± 0.96)	-0.68 (± 1.15)	-0.59 (± 1.00)	-0.60 (± 1.01)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: IU/L				
arithmetic mean (standard deviation)				
Stimulation Day 6	-0.80 (± 0.75)	-0.75 (± 0.75)		
Stimulation Day 8	-0.71 (± 0.94)	-0.83 (± 0.82)		
End-of-stimulation visit	-0.80 (± 1.02)	-0.67 (± 0.86)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[166]
P-value	= 0.5027
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.96

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.08

Notes:

[166] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[167]
P-value	= 0.6268
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.16

Notes:

[167] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[168]
P-value	= 0.2721
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.2

Notes:

[168] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[169]
P-value	= 0.5182
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.17

Notes:

[169] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 6)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[170]
P-value	= 0.892
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.11

Notes:

[170] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[171]
P-value	= 0.5371
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.2

Notes:

[171] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[172]
P-value	= 0.0608
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.32

Notes:

[172] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[173]
P-value	= 0.101
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.3

Notes:

[173] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[174]
P-value	= 0.0118
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.04
upper limit	1.38

Notes:

[174] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (Stimulation Day 8)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[175]
P-value	= 0.1043
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.29

Notes:

[175] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[176]
P-value	= 0.3746
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.21

Notes:

[176] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[177]
P-value	= 0.3276
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.22

Notes:

[177] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[178]
P-value	= 0.1474
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.26

Notes:

[178] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	Placebo and Follitropin Delta v FE 999302 (8 µg) and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[179]
P-value	= 0.3032
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.23

Notes:

[179] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Statistical analysis title	FE 999302, Placebo (End-of-stimulation)
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[180]
P-value	= 0.4131
Method	ANCOVA
Parameter estimate	Ratio vs Placebo
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.08

Notes:

[180] - Treatment groups were compared using multiplicative ANCOVA model with treatment, age strata, and AMH group as factors, and concentration on stimulation Day 1 as a covariate.

Secondary: Positive βhCG (positive serum βhCG test 13-15 days after transfer)

End point title	Positive βhCG (positive serum βhCG test 13-15 days after transfer)

End point description:

Positive βhCG rate was defined as positive serum βhCG test 13-15 days after transfer.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

13-15 days after blastocyst transfer

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: Number of positive subjects				
number (not applicable)	36	40	45	51

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: Number of positive subjects				
number (not applicable)	43	52		

Statistical analyses

Statistical analysis title	FE 999302, Placebo
Comparison groups	Placebo and Follitropin Delta v FE 999302 (1 µg) and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[181]
P-value	= 0.0264
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	0.93

Notes:

[181] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[182]
P-value	= 0.1293
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	1.13

Notes:

[182] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[183]
P-value	= 0.5392
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	1.47

Notes:

[183] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[184]
P-value	= 0.7899
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.6

Notes:

[184] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[185]
P-value	= 0.2208
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	1.23

Notes:

[185] - Logistic regression model with treatment, age strata, and AMH group as factors.

Secondary: Clinical pregnancy (at least one gestational sac 5-6 weeks after transfer)

End point title	Clinical pregnancy (at least one gestational sac 5-6 weeks after transfer)

End point description:

Clinical pregnancy was defined as at least one gestational sac 5-6 weeks after transfer.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

5-6 weeks after blastocyst transfer

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: Number of positive subjects				
number (not applicable)	32	34	44	48

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: Number of positive subjects				
number (not applicable)	40	51		

Statistical analyses

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[186]
P-value	= 0.0081
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.46

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	0.82

Notes:

[186] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[187]
P-value	= 0.0242
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	0.92

Notes:

[187] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[188]
P-value	= 0.5407
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	1.47

Notes:

[188] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[189]
P-value	= 0.5971
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.49

Notes:

[189] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[190]
P-value	= 0.1325
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	1.14

Notes:

[190] - Logistic regression model with treatment, age strata, and AMH group as factors.

Secondary: Vital pregnancy (at least one intrauterine gestational sac with fetal heart beat 5-6 weeks after transfer)

End point title	Vital pregnancy (at least one intrauterine gestational sac with fetal heart beat 5-6 weeks after transfer)

End point description:

Vital pregnancy was defined at least one intrauterine gestational sac with fetal heart beat 5-6 weeks after transfer.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

5-6 weeks after blastocyst transfer

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: Number of positive subjects				
number (not applicable)	30	31	41	43

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: Number of positive subjects				
number (not applicable)	37	45		

Statistical analyses

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[191]
P-value	= 0.031
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	0.94

Notes:

[191] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[192]
P-value	= 0.0589
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.57

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	1.02

Notes:

[192] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[193]
P-value	= 0.8116
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.64

Notes:

[193] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[194]
P-value	= 0.7012
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	1.56

Notes:

[194] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[195]
P-value	= 0.2665
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	1.28

Notes:

[195] - Logistic regression model with treatment, age strata, and AMH group as factors.

Secondary: Ongoing pregnancy (at least one intrauterine viable fetus 10-11 weeks after transfer)

End point title	Ongoing pregnancy (at least one intrauterine viable fetus 10-11 weeks after transfer)

End point description:

Ongoing pregnancy was defined as at least one intrauterine viable fetus 10-11 weeks after transfer.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

10-11 weeks after blastocyst transfer

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: Number of positive subjects				
number (not applicable)	30	30	39	40

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: Number of positive subjects				
number (not applicable)	32	45		

Statistical analyses

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[196]
P-value	= 0.0307
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	0.94

Notes:

[196] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[197]
P-value	= 0.041
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	0.98

Notes:

[197] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[198]
P-value	= 0.5934
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	1.51

Notes:

[198] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[199]
P-value	= 0.4221
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.39

Notes:

[199] - Logistic regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[200]
P-value	= 0.065
Method	Logistic regression model
Parameter estimate	Odds ratio (OR)
Point estimate	0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	1.03

Notes:

[200] - Logistic regression model with treatment, age strata, and AMH group as factors.

Secondary: Number of oocytes retrieved

End point title	Number of oocytes retrieved
End point description:	
The number of oocytes retrieved was recorded at the oocyte retrieval visit.	
End point type	Secondary
End point timeframe:	
Day of oocyte retrieval	

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: Number of oocytes retrieved				
arithmetic mean (standard deviation)	10.9 (± 4.8)	10.8 (± 5.6)	10.8 (± 5.2)	11.3 (± 4.9)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: Number of oocytes retrieved				
arithmetic mean (standard deviation)	9.8 (± 4.9)	12.5 (± 6.4)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[201]
P-value	= 0.0075
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	0.96

Notes:

[201] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[202]
P-value	= 0.013
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	0.97

Notes:

[202] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[203]
P-value	= 0.0081
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.96

Notes:

[203] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[204]
P-value	= 0.091
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.02

Notes:

[204] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[205]
P-value	< 0.0001
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	0.88

Notes:

[205] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Secondary: Number of metaphase II oocytes

End point title	Number of metaphase II oocytes

End point description:

Number of oocytes in metaphase II prior to intracytoplasmic sperm injection (ICSI) insemination.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

Prior to insemination

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: Number of oocytes				
arithmetic mean (standard deviation)	8.5 (± 4.0)	8.4 (± 4.9)	8.2 (± 4.5)	8.5 (± 4.3)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: Number of oocytes				
arithmetic mean (standard deviation)	7.4 (± 4.2)	9.7 (± 5.2)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[206]
P-value	= 0.0203
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.97

Notes:

[206] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[207]
P-value	= 0.0269
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.98

Notes:

[207] - Treatment groups were compared using a Negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[208]
P-value	= 0.0078
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.95

Notes:

[208] - Treatment groups were compared using a Negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[209]
P-value	= 0.044
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1

Notes:

[209] - Treatment groups were compared using a Negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[210]
P-value	< 0.0001
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.86

Notes:

[210] - Treatment groups were compared using a Negative binomial regression model with treatment, age strata, and AMH group as factors.

Secondary: Number of fertilised (2 pronuclei [PN]) oocytes

End point title	Number of fertilised (2 pronuclei [PN]) oocytes

End point description:

The number of pronuclei was counted on day 1 after insemination and recorded as 0, 1, 2, or >2. Fertilised oocytes with 2PN were regarded as correctly fertilised.

The analysis population included the FAS which consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

On Day 1 after insemination

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: Number of oocytes				
arithmetic mean (standard deviation)	6.2 (± 3.6)	6.2 (± 3.9)	5.7 (± 3.7)	6.0 (± 3.6)

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: Number of oocytes				
arithmetic mean (standard deviation)	5.2 (± 3.7)	7.4 (± 4.2)		

Statistical analyses

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (1 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[211]
P-value	= 0.0104
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.81

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	0.95

Notes:

[211] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (2 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	other[212]
P-value	= 0.0209
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	0.97

Notes:

[212] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (4 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	other[213]
P-value	= 0.0006
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.88

Notes:

[213] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (8 µg) and Follitropin Delta v Placebo and Follitropin Delta

Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	other[214]
P-value	= 0.0069
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	0.94

Notes:

[214] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Statistical analysis title	FE 999302, Placebo
Comparison groups	FE 999302 (12 µg) and Follitropin Delta v Placebo and Follitropin Delta
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	other[215]
P-value	< 0.0001
Method	Negative binomial regression model
Parameter estimate	Ratio vs Placebo
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.82

Notes:

[215] - Treatment groups were compared using a negative binomial regression model with treatment, age strata, and AMH group as factors.

Secondary: Incidence of ovarian hyperstimulation syndrome (OHSS) (early or late, any grade)

End point title	Incidence of ovarian hyperstimulation syndrome (OHSS) (early or late, any grade)

End point description:

Early OHSS was defined as OHSS with onset ≤9 days after triggering of final follicular maturation (including OHSS with onset before triggering and OHSS with onset during stimulation where triggering was not performed). Late OHSS was defined as OHSS with onset >9 days after triggering of final follicular maturation.

The safety analysis set was identical to the FAS (including allocation to treatment). The FAS consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

From stimulation Day 1 to end-of-trial

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: Number of subjects				
number (not applicable)				
All OHSS (Any grade)	6	2	6	11
All early OHSS (Any grade)	3	2	4	7
All late OHSS (Any grade)	3	0	2	4

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: Number of subjects				
number (not applicable)				
All OHSS (Any grade)	4	12		
All early OHSS (Any grade)	3	6		
All late OHSS (Any grade)	1	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence and intensity of adverse events

End point title	Incidence and intensity of adverse events

End point description:

The adverse events (AEs) occurring after start of IMP and before the end-of-trial visit, or a pre-treatment AE or pre-existing medical condition that worsens in intensity after start of FE 999302 or placebo treatment and before the end-of-trial visit were considered treatment-emergent AEs and are presented for this endpoint. Intensity of AEs was classified as mild, moderate or severe and is also presented for this endpoint.

The safety analysis set was identical to the FAS (including allocation to treatment). The FAS consisted of all subjects who were randomised and started treatment with FE 999302 or placebo. Subjects were analysed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

From screening to end-of-trial (estimated maximum of 4 months from start of stimulation)

End point values	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta	FE 999302 (8 µg) and Follitropin Delta
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	101	99	107
Units: Number of subjects				
number (not applicable)				
All AEs	47	40	48	56
Mild AEs	40	33	37	45
Moderate AEs	17	9	16	14
Severe AEs	0	5	1	3

End point values	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104	104		
Units: Number of subjects				
number (not applicable)				
All AEs	44	50		
Mild AEs	37	38		
Moderate AEs	12	17		
Severe AEs	1	5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
The AEs were recorded from From screening to end-of-trial	
Adverse event reporting additional description:	
Adverse events occurring after start of IMP and before the end-of-trial visit, or a pre-treatment AE or pre-existing medical condition that worsens in intensity after start of FE 999302 or placebo treatment and before the end-of-trial visit (treatment-emergent AEs) are presented for the safety analysis set.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups	
Reporting group title	FE 999302 (1 µg) and Follitropin Delta
Reporting group description:	
Dose 1 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	FE 999302 (2 µg) and Follitropin Delta
Reporting group description:	
Dose 2 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	FE 999302 (4 µg) and Follitropin Delta
Reporting group description:	
Dose 4 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	FE 999302 (8 µg) and Follitropin Delta
Reporting group description:	
Dose 8 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	FE 999302 (12 µg) and Follitropin Delta
Reporting group description:	
Dose 12 µg of FE 999302, a rhCG solution for subcutaneous injection; individualised follitropin delta dose	
Reporting group title	Placebo and Follitropin Delta
Reporting group description:	
Placebo and individualised follitropin delta dose	

Serious adverse events	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 104 (0.96%)	1 / 101 (0.99%)	1 / 99 (1.01%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 104 (0.00%)	0 / 101 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 104 (0.00%)	0 / 101 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion threatened			
subjects affected / exposed	1 / 104 (0.96%)	0 / 101 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting in pregnancy			
subjects affected / exposed	0 / 104 (0.00%)	0 / 101 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian hyperstimulation syndrome			
subjects affected / exposed	0 / 104 (0.00%)	0 / 101 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adnexal torsion			
subjects affected / exposed	0 / 104 (0.00%)	0 / 101 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 104 (0.00%)	1 / 101 (0.99%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	FE 999302 (8 µg) and Follitropin Delta	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 107 (2.80%)	2 / 104 (1.92%)	3 / 104 (2.88%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			

subjects affected / exposed	1 / 107 (0.93%)	0 / 104 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 107 (0.00%)	1 / 104 (0.96%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion threatened			
subjects affected / exposed	0 / 107 (0.00%)	0 / 104 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting in pregnancy			
subjects affected / exposed	0 / 107 (0.00%)	0 / 104 (0.00%)	1 / 104 (0.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian hyperstimulation syndrome			
subjects affected / exposed	1 / 107 (0.93%)	1 / 104 (0.96%)	2 / 104 (1.92%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adnexal torsion			
subjects affected / exposed	1 / 107 (0.93%)	0 / 104 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 107 (0.00%)	0 / 104 (0.00%)	0 / 104 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	FE 999302 (1 µg) and Follitropin Delta	FE 999302 (2 µg) and Follitropin Delta	FE 999302 (4 µg) and Follitropin Delta
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 104 (26.92%)	19 / 101 (18.81%)	32 / 99 (32.32%)
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	1 / 104 (0.96%)	2 / 101 (1.98%)	4 / 99 (4.04%)
occurrences (all)	1	2	4
Nervous system disorders			
Headache			
subjects affected / exposed	11 / 104 (10.58%)	8 / 101 (7.92%)	13 / 99 (13.13%)
occurrences (all)	12	9	13
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 104 (0.96%)	2 / 101 (1.98%)	5 / 99 (5.05%)
occurrences (all)	1	2	5
Biochemical pregnancy			
subjects affected / exposed	4 / 104 (3.85%)	6 / 101 (5.94%)	1 / 99 (1.01%)
occurrences (all)	4	6	1
Reproductive system and breast disorders			
Ovarian hyperstimulation syndrome			
subjects affected / exposed	6 / 104 (5.77%)	2 / 101 (1.98%)	5 / 99 (5.05%)
occurrences (all)	6	2	5
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	2 / 104 (1.92%)	0 / 101 (0.00%)	6 / 99 (6.06%)
occurrences (all)	3	0	6
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	6 / 104 (5.77%)	1 / 101 (0.99%)	3 / 99 (3.03%)
occurrences (all)	6	1	3

Non-serious adverse events	FE 999302 (8 µg) and Follitropin Delta	FE 999302 (12 µg) and Follitropin Delta	Placebo and Follitropin Delta
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 107 (35.51%)	30 / 104 (28.85%)	34 / 104 (32.69%)
Injury, poisoning and procedural complications			

Procedural pain			
subjects affected / exposed	4 / 107 (3.74%)	2 / 104 (1.92%)	7 / 104 (6.73%)
occurrences (all)	4	2	7
Nervous system disorders			
Headache			
subjects affected / exposed	18 / 107 (16.82%)	15 / 104 (14.42%)	11 / 104 (10.58%)
occurrences (all)	22	17	13
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	6 / 107 (5.61%)	5 / 104 (4.81%)	3 / 104 (2.88%)
occurrences (all)	6	5	3
Biochemical pregnancy			
subjects affected / exposed	3 / 107 (2.80%)	3 / 104 (2.88%)	5 / 104 (4.81%)
occurrences (all)	3	3	5
Reproductive system and breast disorders			
Ovarian hyperstimulation syndrome			
subjects affected / exposed	10 / 107 (9.35%)	3 / 104 (2.88%)	10 / 104 (9.62%)
occurrences (all)	10	3	10
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	7 / 107 (6.54%)	3 / 104 (2.88%)	2 / 104 (1.92%)
occurrences (all)	7	3	2
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 107 (1.87%)	3 / 104 (2.88%)	1 / 104 (0.96%)
occurrences (all)	3	3	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 March 2020	Amendment 04 (version 1.0, dated 19 March 2020) was a substantial amendment issued as urgent safety measures due to COVID-19 required to protect subjects against immediate hazard to their health and safety. The amendment included guidance for continued trial conduct and management of subjects included in the trial.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported