



## Clinical trial results: FITMI - First In Treating Male Infertility Summary

EudraCT number	2021-003451-42
Trial protocol	DK
Global end of trial date	22 October 2024

### Results information

Result version number	v1 (current)
This version publication date	12 November 2025
First version publication date	12 November 2025
Summary attachment (see zip file)	Trial results published (Effect of denosumab on semen quality in infertile men selected by serum level of antimüllerian hormone - a randomized controlled trial.pdf)

### Trial information

#### Trial identification

Sponsor protocol code	19642021
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#### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	Dept. Growth and Reproduction
Sponsor organisation address	Blegdamsvej 9, Copenhagen , Denmark,
Public contact	Sekretariatet, Dept. of Growth and Reproduction, fitmi.rigshospitalet@regionh.dk
Scientific contact	Sekretariatet, Dept. of Growth and Reproduction, fitmi.rigshospitalet@regionh.dk

Notes:

#### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	01 February 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 October 2024
Global end of trial reached?	Yes
Global end of trial date	22 October 2024
Was the trial ended prematurely?	Yes

Notes:

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**General information about the trial**

Main objective of the trial:

The aim of this intervention is to investigate whether Denosumab can improve semen quality in a sub-group of infertile men.

Protection of trial subjects:

Calcium and vitamin D to avoid hypocalcemia

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 February 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	Denmark: 181
Worldwide total number of subjects	181
EEA total number of subjects	181

Notes:

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**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)	181
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

From andrological clinic at growth and reproduction, RH Denmark

### Pre-assignment

Screening details:

Some were referred for infertility

### Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Denosumab

Arm description:

60 mg sc once

Arm type	Experimental
Investigational medicinal product name	denosumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

60 mg sc

<b>Arm title</b>	placebo
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Arm description: -

Arm type	Placebo
Investigational medicinal product name	Nacl saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

1 mL

<b>Number of subjects in period 1</b>	Denosumab	placebo
Started	91	90
Completed	85	85
Not completed	6	5
Lost to follow-up	6	5



## Baseline characteristics

### Reporting groups

Reporting group title

Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	181	181	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	181	181	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	34.0		
standard deviation	± 4.8	-	
Gender categorical			
Units: Subjects			
Female	0	0	
Male	181	181	

## End points

### End points reporting groups

Reporting group title	Denosumab
Reporting group description:	
60 mg sc once	
Reporting group title	placebo
Reporting group description: -	

### Primary: Sperm concentration

End point title	Sperm concentration
End point description:	
End point type	Primary
End point timeframe:	
80 days	

End point values	Denosumab	placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	85	85		
Units: million/mL				
median (inter-quartile range (Q1-Q3))	11 (6.7 to 18)	12 (6.8 to 20.3)		

### Statistical analyses

Statistical analysis title	Ancova
Comparison groups	Denosumab v placebo
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	ANCOVA

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

180 days

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	none
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Dictionary version	0
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### Reporting groups

Reporting group title	Denosumab
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Reporting group description: -

Reporting group title	Placebo
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Reporting group description: -

Serious adverse events	Denosumab	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 91 (2.20%)	0 / 90 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 91 (2.20%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Denosumab	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 91 (16.48%)	14 / 90 (15.56%)	
Infections and infestations			
Infection			
subjects affected / exposed	15 / 91 (16.48%)	14 / 90 (15.56%)	
occurrences (all)	15	14	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported