Clinical trial results:
Denosumab and male infertility: a prospective intervention study

Summary

EudraCT number	2015-000655-24
Trial protocol	DK
Global end of trial date	10 May 2016

Results information

Result version number	v1 (current)
This version publication date	25 June 2021
First version publication date	25 June 2021
Summary attachment (see zip file)	RANKL regulates male reproductive function (RANKL regulates male reproductive function.pdf)

Trial information

Trial identification

Sponsor protocol code	CBG-study2

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Dept. of growth and reproduction
Sponsor organisation address	Blegdamsvej 9, copenhagen, Denmark, 2100
Public contact	martin blomberg jensen, rigshospitalet, 45 35451865, blombergjensen@gmail.com
Scientific contact	martin blomberg jensen, rigshospitalet, 45 35451865, blombergjensen@gmail.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	Final
Date of interim/final analysis	10 January 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 April 2016
Global end of trial reached?	Yes
Global end of trial date	10 May 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

to investigate whether short term Denosumab treatment can imporve sperm count and male fertility

Protection of trial subjects:

regular blood sampling and clinical controls at department

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 March 2015
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	Denmark: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	12
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

through out patient clinic

Pre-assignment

Screening details:

male infertility

Period 1

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

Blinding implementation details:

no blinding. Only one arm

Arms

Arm title	Denosumab

Arm description:

denosumab

Arm type	Experimental
Investigational medicinal product name	denosumab
Investigational medicinal product code	9001231
Other name	prolia
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

60 mg s.c. once

Number of subjects in period 1	Denosumab
Started	12
Completed	10
Not completed	2
excluded as per protocol due to high fever	1
Lost to follow-up	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Denosumab
Reporting group description: denosumab	

Primary: change in semen concentration

End point title	change in semen concentration[1]
End point description:	
End point type	Primary
End point timeframe: 180 days	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There is only ONE ARM in this study. We performed ANOVA with Dunnett's post hoc test, comparing changes in semen quality to baseline values.

End point values	Denosumab			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: mill/ml				
number (not applicable)	10			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

180 days

Assessment type	Systematic

Dictionary used

Dictionary name	ICD10
Dictionary version	1

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: We did not experince non-serious adverse events

Serious adverse events	overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Surgical and medical procedures			
Appendicitis	Additional description: one man had an appendicitis during the study period. This was assessed as UNRELATED TO IMP		
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/33893301