# 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:<br>denosumab | |

### Primary: change in semen concentration

| | |
|---|---|
| End point title | change in semen concentration[1] |
| End point description: | |
| End point type | Primary |
| End point timeframe:<br>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