



Clinical trial results:

Vitamin D supplementation and male infertility: a randomized double blinded clinical trial

Summary

EudraCT number	2010-024588-42
Trial protocol	DK
Global end of trial date	26 January 2015

Results information

Result version number	v1 (current)
This version publication date	29 March 2022
First version publication date	29 March 2022
Summary attachment (see zip file)	Final publication (D-vit Martin RCT FINAL.pdf)

Trial information

Trial identification

Sponsor protocol code	2010124801
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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. of Growth and Reproduction, Rigshospitalet
Sponsor organisation address	Blegdamsvej 9, København Ø, Denmark, 2100
Public contact	MD, PhD, Niels Jørgensen , Dept. of Growth and Reproduction , blombergjensen@gmail.com
Scientific contact	MD, PhD, Niels Jørgensen , Dept. of Growth and Reproduction , +45 35459592, 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	25 July 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 August 2014
Global end of trial reached?	Yes
Global end of trial date	26 January 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate whether vitamin D supplementation to vitamin D deficient or insufficient men improves semen quality and male fertility

Protection of trial subjects:

During intervention period trial subjects had the opportunity to contact the outpatient clinic, with questions or symptoms.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 January 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 307
Worldwide total number of subjects	307
EEA total number of subjects	307

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)	307
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 1427 men were referred with male infertility and screened . Of these, 330 infertile men formed the study cohort: 1002 men did not meet all inclusion criteria or met an exclusion criterion, and 95 men were eligible but did not wish to participate. The main reasons for exclusion were high vitamin D status, comorbidities or azoospermia.

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Vitamin D

Arm description:

cholecalciferol

Arm type	Experimental
Investigational medicinal product name	Cholecalciferol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Infertile men were randomly assigned 1:1 to either placebo or an initial oral dose of 300,000 IU of cholecalciferol dissolved in oil, followed by receipt of tablets consisting of cholecalciferol 1400 IU and calcium 500 mg once daily for 150 days (Pfizer, Copenhagen, Denmark).

Arm title	placebo
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Arm description:

Placebo tbl

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

calcium 500 mg x 1 daily

Number of subjects in period 1	Vitamin D	placebo
Started	151	156
Completed	133	136
Not completed	18	20
Lost to follow-up	18	20

Baseline characteristics

End points

End points reporting groups

Reporting group title	Vitamin D
Reporting group description:	
cholecalciferol	
Reporting group title	placebo
Reporting group description:	
Placebo tbl	

Primary: Differences in semen quality

End point title	Differences in semen quality
End point description:	
End point type	Primary
End point timeframe:	
150 days	

End point values	Vitamin D	placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	136	133		
Units: Number pr. million				
median (inter-quartile range (Q1-Q3))	12.8 (3.4 to 32.3)	13.3 (4.2 to 38.5)		

Statistical analyses

Statistical analysis title	BIOSTATISTICAL ANALYSIS
Comparison groups	Vitamin D v placebo
Number of subjects included in analysis	269
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Mixed models analysis
Parameter estimate	Median difference (final values)

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

January 2011 to January 2015

Assessment type	Systematic
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Dictionary used

Dictionary name	GCP
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Dictionary version	1
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Reporting groups

Reporting group title	pancreatitis
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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: please see attachment for details

Serious adverse events	pancreatitis		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 307 (0.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Gastrointestinal disorders			
Pancreatitis acute			
subjects affected / exposed	1 / 307 (0.33%)		
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	pancreatitis		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 307 (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/29126319>