Clinical trial results:
Odense Androgen Study - The effect of Testim vs strength training i a populationbased, randomised, placebocontrolled, doubleblinded study in hypogonadal men

Summary

EudraCT number	2007-001690-28
Trial protocol	DK
Global end of trial date	20 September 2009

Results information

Result version number	v1 (current)
This version publication date	14 November 2020
First version publication date	14 November 2020

Trial information

Trial identification

Sponsor protocol code	22978379

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00700024
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Odense University Hospital
Sponsor organisation address	kløvervænget 6, Odense, Denmark,
Public contact	Department of Endocrinology, Odense University Hospital, department of Endocrinology, +45 65412502,
Scientific contact	Marianne Andersen, Odense University Hospital, department of Endocrinology, +45 65412502, msa@rsyd.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:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 October 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 September 2009
Global end of trial reached?	Yes
Global end of trial date	20 September 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1) The effect of Testosterone (testim) in a randomized doubleblinded plcebocontrolled study on body composition, liverfat and cardiovascular risk parameters
2) The Effect of training on body composition, liverfat and cardiovascular risk parameters
3)Compare the effect of testosterone and training on body composition, liverfat and cardiovascular risk parameters
4) Investigate the effect of training on the serum level of Testosterone

Protection of trial subjects:

as requested by national authority

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 August 2008
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: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	40
From 65 to 84 years	20
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Men aged 60+, waist >94 cm and bioavailable testosterone < 7.3 nmol/L

Pre-assignment

Screening details:

Men aged 60+, waist >94 cm and bioavailable testosterone < 7.3 nmol/L

Period 1

Period 1 title	Baseline (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
Arm title	Testosterone

Arm description:

testim gel 5-10 g/dag

Arm type	Active comparator
Investigational medicinal product name	Testim
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

50-100 mg testosterone gel/dag

Arm title	Placebo

Arm description:

PLacebo gel for 6 months

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

5-10 g gel/day

Arm title	Strengh training + testim

Arm description:

strenth training for 6 months (+ testim for the last 3 months)

Arm type	training
Investigational medicinal product name	Testim
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:
50-100 mg testosterone gel/dag

Arm title	Strenght training + placebo

Arm description:
Stength training for 6 months (+ placebo for the last 3 months)

Arm type	training
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:
5-10 g gel/day

Number of subjects in period 1	Testosterone	Placebo	Strengh training + testim
Started	20	20	10
Completed	20	20	10

Number of subjects in period 1	Strenght training + placebo
Started	10
Completed	10

Baseline characteristics

Reporting groups	
Reporting group title	Testosterone
Reporting group description:	
testim gel 5-10 g/dag	
Reporting group title	Placebo
Reporting group description:	
PLacebo gel for 6 months	
Reporting group title	Strengh training + testim
Reporting group description:	
strenth training for 6 months (+ testim for the last 3 months)	
Reporting group title	Strenght training + placebo
Reporting group description:	
Stength training for 6 months (+ placebo for the last 3 months)	

Reporting group values	Testosterone	Placebo	Strengh training + testim
Number of subjects	20	20	10
Age categorical			
Men 60 +			
Units: Subjects			
Adults (18-64 years)	15	15	5
From 65-84 years	5	5	5
Age continuous			
men 60 +			
Units: years			
median	69	69	69
full range (min-max)	60 to 78	60 to 78	60 to 78
Gender categorical			
men			
Units: Subjects			
Female	0	0	0
Male	20	20	10

Reporting group values	Strenght training + placebo	Total	
Number of subjects	10	60	
Age categorical			
Men 60 +			
Units: Subjects			
Adults (18-64 years)	5	40	
From 65-84 years	5	20	
Age continuous			
men 60 +			
Units: years			
median	69		
full range (min-max)	60 to 78	-	

Gender categorical			
men			
Units: Subjects			
Female	0	0	
Male	10	60	

End points

End points reporting groups

Reporting group title	Testosterone
Reporting group description: testim gel 5-10 g/dag	
Reporting group title	Placebo
Reporting group description: PLacebo gel for 6 months	
Reporting group title	Strengh training + testim
Reporting group description: strenth training for 6 months (+ testim for the last 3 months)	
Reporting group title	Strenght training + placebo
Reporting group description: Stength training for 6 months (+ placebo for the last 3 months)	
Subject analysis set title	lean body mass
Subject analysis set type	Full analysis
Subject analysis set description: analysis of change in lean body mass after 6 months	

Primary: lean body mass

End point title	lean body mass
End point description: change in lean body mass	
End point type	Primary
End point timeframe: 6 months	

End point values	Testosterone	Placebo	Strengh training + testim	Strenght training + placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	18	10	10
Units: kg				
arithmetic mean (standard deviation)	64.3 (± 7.6)	66.3 (± 8.2)	64.3 (± 7.6)	66.3 (± 8.2)

Statistical analyses

Statistical analysis title	Statistical analysis
Statistical analysis description: The outcomes was compares by multiple linear regression analysis controlled for baseline values	
Comparison groups	Testosterone v Placebo

Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.05
Method	Regression, Linear
Confidence interval	
level	95 %
sides	2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: as requested by authority	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	1
Reporting groups	
Reporting group title	testosterone
Reporting group description: -	
Reporting group title	placebo
Reporting group description: -	
Reporting group title	strength training
Reporting group description: -	

Serious adverse events	testosterone	placebo	strength training
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

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

Non-serious adverse events	testosterone	placebo	strength training
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 20 (25.00%)	5 / 20 (25.00%)	0 / 20 (0.00%)
Skin and subcutaneous tissue disorders			
rash			
subjects affected / exposed	5 / 20 (25.00%)	5 / 20 (25.00%)	0 / 20 (0.00%)
occurrences (all)	5	5	5

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/22190001

http://www.ncbi.nlm.nih.gov/pubmed/21347608

http://www.ncbi.nlm.nih.gov/pubmed/22918704