



## Clinical trial results:

### Odense Androgen Study - The effect of Testim vs strength training in 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 | klørvænget 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 placebocontrolled 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 |
|------------------------------|-----|

|                  |              |
|------------------|--------------|
| <b>Arm title</b> | 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

|                  |         |
|------------------|---------|
| <b>Arm title</b> | 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

|                  |                            |
|------------------|----------------------------|
| <b>Arm title</b> | Strength 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

|                  |                             |
|------------------|-----------------------------|
| <b>Arm title</b> | 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

| <b>Number of subjects in period 1</b> | Testosterone | Placebo | Strenght training +<br>testim |
|---------------------------------------|--------------|---------|-------------------------------|
| Started                               | 20           | 20      | 10                            |
| Completed                             | 20           | 20      | 10                            |

| <b>Number of subjects in period 1</b> | Strenght training +<br>placebo |
|---------------------------------------|--------------------------------|
| Started                               | 10                             |
| Completed                             | 10                             |

## Baseline characteristics

### Reporting groups

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

| Reporting group values | Testosterone | Placebo  | Strenght training +<br>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 +<br>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:<br>testim gel 5-10 g/dag   |                             |
| Reporting group title   | Placebo                     |
| Reporting group description:<br>PLacebo gel for 6 months  |                             |
| Reporting group title   | Strenght training + testim  |
| Reporting group description:<br>strenght training for 6 months (+ testim for the last 3 months) |                             |
| Reporting group title   | Strenght training + placebo |
| Reporting group description:<br>Stenght 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:<br>analysis of change in lean body mass after 6 months        |                             |

### Primary: lean body mass

|  |                |
|--|----------------|
| End point title                                    | lean body mass |
| End point description:<br>change in lean body mass |                |
| End point type                                     | Primary        |
| End point timeframe:<br>6 months                   |                |

| End point values                     | Testosterone      | Placebo           | Strenght 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 ( $\pm$ 7.6) | 66.3 ( $\pm$ 8.2) | 64.3 ( $\pm$ 7.6)          | 66.3 ( $\pm$ 8.2)           |

### Statistical analyses

|  |                        |
|--|------------------------|
| Statistical analysis title   | Statistical analysis   |
| Statistical analysis description:<br>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

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

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### 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>