Zoetermeer Study.

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The study hypothesis is that that daily oral atamestane (100 mg/day), dehydroepiandrosterone (50 mg/day) alone and the combined regimen improve physical frailty, muscle strength and functional performance compared to placebo.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28735

Bron
NTR

Verkorte titel
N/A

Aandoening

Physical frailty

Ondersteuning

Primaire sponsor: Schering Berlin, SBU FC & HT/Department HT

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Isometric Grip Strength;<br
2. Leg Extension Power;
3. Physical Performance (according to Guralnik).

Toelichting onderzoek

Achtergrond van het onderzoek

The Zoetermeer Study is double-blind randomised, placebo-controlled clinical study to investigate the effects of daily oral atamestane (100 mg/day) and dehydroepiandrosterone (50 mg/day) alone and in a combined regimen on physical frailty and quality of life in 100 elderly male volunteers over a treatment period of 36 weeks. The trial has been finished, and a study report is in preparation.

Doel van het onderzoek

The study hypothesis is that that daily oral atamestane (100 mg/day), dehydroepiandrosterone (50 mg/day) alone and the combined regimen improve physical frailty, muscle strength and functional performance compared to placebo.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Atamestane (100 mg/day), - dehydroepiandrosterone (50 mg/day),
the combined regimen of atamestane (100 mg/day) and dehydroepiandrosterone (50 mg/day).

Contactpersonen

Publiek

Erasmus Medical Center,
Department of Internal Medicine,
Molewaterplein 40
A.W. Beld, van den
Molewaterplein 40
Rotterdam 3015 GD
The Netherlands
+31 (0)10 4639222

Wetenschappelijk

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Department of Internal Medicine,
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Rotterdam 3015 GD
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Men;

2. 70 years or older;

3. Participant in previous cross-sectional study among 400 men;

4. Low performance score on IGS and LEP test compared to mean of 400 men in cross-sectional study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Severe arthropathic deformation of knee joint severly limiting mobility;

2. Severe systemic disease interfering with conduct of study or interpretation of results;

3. Abnormal lab functions from preceding cross-sectional study considered clinically significant and giving suspicion of specific organ dysfunction;

4. Myocardial infarction within 6 months prior to first visit or clinical evidence of congestive heart failure;

5. History of stroke or TIAs;

6. Sitting systolic blood rpessure of 200 mmHg or higher or diastolic blood pressure of 105 mmHg or higher at any of pretreatment visits;

7. Active malignant disease with significant impact of physical condition;

8. History of prostatic cancer;

9. Diabetes mellitus treated with insulin;

10. Preexisting signs of abnormal liver function with clinical significance;

11. History of alcohol abuse within last 2 years;

12. Participation in another clinical trial or systemic administration of an investigational drug within the last 3 months prior to start of study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-1996
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	07-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL226
NTR-old	NTR263
Ander register	: ME95159
ISRCTN	ISRCTN72714576

Resultaten

Samenvatting resultaten
J Clin Endocrinol Metab. 2006 Oct;91(10):3988-91. Epub 2006 Jun 27.