Zoetermeer Study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28735

Source
NTR

Brief title
N/A

Health condition

Physical frailty

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. Isometric Grip Strength;

3. Physical Performance (according to Guralnik).

Secondary outcome

1. Activities od Daily Living;

2. Fragen of LiebensZufriedenheid (quality of life);

3. Mini Mental State examination;

4. Body composition;

5. Bone density of hip;

6. Bone metabolism;

7. Hormonal parameters total testosterone, DHEA, DHEA-S, estradiol, estrone, SHBG, IGF-1, IGFBP, IGFBP3;

8. Glucose, insulin HbA1c;

9. Immunological parameters (lymphocyte sub-populations and surface markers);

10. Lipid metabolism (HDL, LDL, triglycerides, cholesterol);

11. Carotid intima-media thickness.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

Atamestane (100 mg/day), - dehydroepiandrosterone (50 mg/day),

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

Contacts

Public
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
Scientific
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

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-1996

Enrollment:	100
Type:	Actual

Ethics review

Positive opinion Date:	07-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

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