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Zoetermeer Study: 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

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
17/09/2008

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ME95159; NTR263

Study information

Scientific Title

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, double blind, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Physical frailty

Interventions
1. Atamestane (100 mg/day)
2. Dehydroepiandrosterone (50 mg/day)
3. Combined regimen of atamestane (100 mg/day) and dehydroepiandrosterone (50 mg/day)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Atamestane, dehydroepiandrosterone

Primary outcome measure
1. Isometric grip strength
2. Leg extension power
3. Physical performance (according to Guralnik)

Secondary outcome measures
1. Activities of Daily Living
2. Quality of life
3. Mini Mental State Examination
4. Body composition
5. Bone density of hip
6. Bone metabolism
7. Hormonal parameters total testosterone, dehydroepiandrosterone (DHEA), dehydroepiandrosterone sulphate (DHEAS), oestradiol, oestrone, sex hormone binding globulin (SHBG), insulin-like growth factor 1 (IGF-1), IGF-binding proteins (IGFBP), IGF-binding protein 3 (IGFBP3)
8. Glucose, insulin HbA1c
9. Immunological parameters (lymphocyte sub-populations and surface markers)
10. Lipid metabolism (high density lipoproetin [HDL], low density lipoprotein [LDL], triglycerides, cholesterol)
11. Carotid intima-media thickness

Overall study start date
01/01/1996

Completion date
31/08/1997

Eligibility

Key inclusion criteria
1. Men
2. 70 years or older
3. Participant in previous cross-sectional study among 400 men
4. Low performance score on isometric grip strength (IGS) and leg extensor power (LEP) test compared to mean of 400 men in cross-sectional study

Participant type(s)
Patient

Age group
Senior

Sex
Male

Target number of participants
100

Key exclusion criteria
1. Severe arthropathic deformation of knee joint severely 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 transient ischaemic attacks (TIAs)
6. Sitting systolic blood pressure 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

Date of first enrolment
01/01/1996

Date of final enrolment
31/08/1997

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Amsterdam
Netherlands
3015 GD

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

Sponsor details
Dr Molewaterplein 40/50
Rotterdam
Netherlands
3000 CA

Sponsor type
University/education

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Industry

Funder Name
Schering AG (Germany) - Strategic Business Unit Fertility Control and Hormone Therapy (SBU FC /HT)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration