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A double-blind placebo-controlled trial of the effect of perindopril on muscle strength and functional capacity in older people

Submission date
25/01/2005

Recruitment status
No longer recruiting

Registration date
31/03/2005

Overall study status
Completed

Last Edited
21/05/2018

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Recent research suggests that a medicine called perindopril that is commonly used in patients with heart problems could have a beneficial effect on muscle function. An improvement in muscle function means that less effort is needed with day to day activities and that exercise ability may improve. Perindopril has not been tested in a trial to see if giving perindopril does indeed improve physical function. The aim of this study is therefore to find out if perindopril improves walking distance and quality of life in older people with functional impairment.

Who can participate?
Older people over the age of 65 years with some dependence in activities of daily living

What does the study involve?
The study lasts for 20 weeks. At the start of the study, participants are randomly allocated to take. either perindopril or matching placebo (dummy) capsules once a day for the 20 weeks of the study. Participants are assessed at the start of the study, at 10 weeks and at 20 weeks. Each visit lasts one and a half hours. At each visit, participants undergo some or all of the following depending on which visit it is: a heart scan (echo scan), blood pressure measurement, blood sample, walking test, test of ability to get out of a chair, and questionnaires about quality of life and everyday function. Participants are also asked to wear a device on their belt (an accelerometer) during the day for a week, to measure how active they are.

What are the possible benefits and risks of participating?
Those who receive the perindopril might improve their muscle function and ability to exercise (if the medication works). Perindopril can uncommonly cause an upset stomach, dizziness or kidney problems with increases in blood levels of potassium. Participants' blood and blood pressure are monitored to minimise the risks.

Where is the study run from?
Ninewells Hospital and Medical School (UK)

When is the study starting and how long is it expected to run for?
August 2003 to February 2006

Who is funding the study?
Chief Scientist Office (UK)

Who is the main contact?
Prof. Marion McMurdo

Contact information

Type(s)
Scientific

Contact name
Prof Marion McMurdo

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CZB/4/88

Study information

Scientific Title
A double-blind placebo-controlled trial of the effect of perindopril on muscle strength and functional capacity in older people

Study objectives
Physical function and exercise capacity decline with age and are a major source of disability in older people. Recent evidence suggests a potential role for the renin-angiotensin system in modulating muscle function. We sought to examine the effect of the angiotensin converting enzyme (ACE) inhibitor perindopril on physical function in elderly people with functional impairment who had no heart failure or left ventricular systolic dysfunction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Committee on Medical Research Ethics, 2003, ref: 196/02

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Sarcopenia

Interventions
Perindopril or placebo given for a period of 20 weeks

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Perindopril

Primary outcome measure
Change in the 6-minute walking distance over the 20 weeks

Secondary outcome measures
1. Changes in muscle function
2. Daily activity levels
3. Self-reported function
4. Health-related quality of life

Overall study start date
06/08/2003

Completion date

06/02/2006

Eligibility

Key inclusion criteria
Older people over the age of 65 years with some dependence in activities of daily living

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
148

Key exclusion criteria
1. Without left ventricular systolic dysfunction
2. Already receiving an angiotensin converting enzyme (ACE) inhibitor or an angiotensin II inhibitor
3. Contraindication to ACE inhibitors
4. Unable to give informed consent

Date of first enrolment
06/08/2003

Date of final enrolment
06/02/2006

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Ninewells Hospital and Medical School
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
Chief Scientist Office of the Scottish Executive Health Department (UK)

Sponsor details
St Andrew's House
Edinburgh
United Kingdom
EH1 3DG

Sponsor type
Government

Website
http://www.sehd.scot.nhs.uk/cso/

ROR
https://ror.org/01bw7zm61

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (ref: CZB/4/88)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

The protocol is available from the authors on request but is not available online. Study data are available for non-commercial, bona-fide academic analyses in collaboration with the authors; decisions on data access will be made between the investigators and the Sponsor (University of Dundee). Participant consent for unrestricted sharing of individual participant data was not obtained. Contact for data sharing: Dr Catrina Forde (c.forde@dundee.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/10/2007		Yes	No
Basic results		16/05/2018	16/05/2018	No	No