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Maximising physical function in later life: angiotensin converting enzyme inhibition and resistance exercise training

Submission date
07/08/2009

Recruitment status
No longer recruiting

Registration date
27/08/2009

Overall study status
Completed

Last Edited
13/04/2018

Condition category
Other

[X] 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. Although perindopril improved muscle function in people who were not exercising, it is unclear if perindopril can enhance the effect of an exercise programme undertaken by older people. The aim of this study is therefore to find out if adding perindopril to exercise therapy will bring benefits over and above the improvement in muscle function seen with exercise alone in older people.

Who can participate?
People aged 65 or over who use a walking aid and/or need help with daily living activities

What does the study involve?
The study lasts for 20 weeks. Everyone in the study is invited to a twice weekly exercise class that is run in small groups. These sessions last about one and a half hours. All exercise is tailored to individual needs. Participants are provided with structured information about exercise. After 10 weeks of exercise classes, they are given an exercise diary and encouragement from a physiotherapist via telephone to keep going with exercise for another 10 weeks. At the start of the study, participants are randomly allocated to take capsules containing either perindopril or a placebo (dummy drug). Participants take one capsule a day for the 20 weeks of the study and attend visits 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 scan of the heart (echo scan), blood pressure measurement, blood sample, walking test, tests of leg strength, arm strength, balance and ability to get out of a chair, and questionnaires about quality of life and everyday function.

What are the possible benefits and risks of participating?
Participating in the exercise classes can increase muscle function and encourage participants to lead a healthy lifestyle. Those who receive the perindopril might additionally improve their

muscle function and ability to exercise (if the medication works). Perindopril uncommonly can 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. Participation in the exercise classes and walking test could lead to mild tiredness.

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

When is the study starting and how long is it expected to run for?
December 2009 to May 2012

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
Ageing and Health
Mailbox 1
Division of Medical Sciences
Ninewells Hospital & Medical School
Dundee
United Kingdom
DD1 9SY

Additional identifiers

EudraCT/CTIS number
2009-012621-12

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol 1.1

Study information

Scientific Title

Maximising physical function in later life: a two-centre randomised controlled trial of progressive resistance exercise training in combination with angiotensin-converting enzyme (ACE) inhibition

Study objectives
Combining angiotensin converting enzyme inhibition and resistance exercise training will confer an advantage over exercise alone for improving physical function in functionally impaired older people.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Service, Ninewells Hospital & Medical School, 06/08/2009, ref: 09/S0501/48

Study design
Double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

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

Interventions
All participants will receive 10 weeks of supervised exercise training followed by 10 weeks of unsupervised home based training. They will be randomised to receive either Perindopril 4 mg or placebo for 20 weeks along with the exercise training.

Contact details for Patient Information Sheet:
Ageing & Health
Mailbox 1
Division of Medical Sciences
Ninewells Hospital & Medical School
Dundee DD1 9SY
T: +44 (0)1382 632436

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Six-minute walking distance, measured at baseline, 10 and 20 weeks

Secondary outcome measures
Measured at baseline, 10 and 20 weeks:
1. Short Physical Performance Battery (score range 0 worst function to 12 best function)
2. Hand grip strength and quadriceps strength measured using dynamometry
3. Functional Limitation Profile questionnaire
4. Health-related quality of life measured using the EuroQol questionnaire

Overall study start date
01/12/2009

Completion date
31/05/2012

Eligibility

Key inclusion criteria
1. Aged 65 years or over, either sex
2. An impairment of mobility requiring the use of a walking aid and/or dependence in functional activities of daily living requiring assistance
3. Short Physical Performance Battery (SPPB) score less than or equal to 10

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
186

Key exclusion criteria
1. Already in receipt of ACE inhibitor or angiotensin-receptor blocker (ARB)
2. Contraindication to ACE inhibitor use (significant aortic outflow obstruction; estimated glomerular filtration rate [eGFR] less than 30 ml/hr; serum potassium greater than 5.0 mmol/l, systolic blood pressure [BP] less than 90 mmHg)

3. Clinical diagnosis of heart failure
4. Undiagnosed heart failure (left ventricular systolic dysfunction on echocardiography)
5. Regular participation in exercise training
6. Moderate to severe cognitive impairment (Mini-Mental State Examination [MMSE] less than 20 /30)
7. Wheelchair bound
8. Unwilling to participate

Date of first enrolment
01/12/2009

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
Scotland

United Kingdom

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

Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
Clinical Trials Unit
Ninewells Hospital & Medical School
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Sponsor type
University/education

Website

http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (ref: CZB/4/708)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol is available from the authors on request but is not available online.

Intention to publish date

Individual participant data (IPD) sharing plan
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	01/06/2014		Yes	No

Basic results	13/04/2018	13/04/2018	No	No
HRA research summary		28/06/2023	No	No