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Spironolactone and exercise capacity in older people

Submission date	**Recruitment status**	[X] Prospectively registered
07/08/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/08/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/11/2017	Other	

Plain English summary of protocol

Background and study aims
Many older people find that they become less strong as they get older, and that this loss of strength interferes with the ability to everyday activities. Loss of strength with age also leads to falls, broken bones, and the need for more help with daily activities. Although exercise works well to improve muscle strength and function even in older people, not everyone can, or wants to, exercise. Finding medications that can improve muscle function may provide an alternative way of treating this problem. Spironolactone is a medicine used to treat heart failure and high blood pressure. There is some evidence that it might have directly beneficial effects on muscle function – separate from its effects on blood pressure or the heart. This idea has not been tested before, and the aim of this study is to test whether spironolactone increases exercise capacity in functionally impaired older people without chronic heart failure.

Who can participate?
People aged 65 and over who have problems with daily living activities

What does the study involve?
Participants are randomly allocated to take either spironolactone or placebo (dummy) capsules for 5 months. Participants visit the hospital three times over the 5 months. Each visit lasts between one and two hours. At each visit, participants perform some walking tests and complete three questionnaires about how much they are able to do and how they feel. They provide details of what medicines they are taking, their blood pressure is measured and blood samples are taken (no more than a few teaspoonfuls). At the start of the study, participants undergo an echocardiography (ultrasound) scan of their heart.

What are the possible benefits and risks of participating?
Spironolactone is a diuretic drug therefore participants may pass more urine than usual. Spironolactone has been used as a medication for 60 years and is safe. However, it can occasionally cause an upset stomach, dizziness or breast enlargement. It can also increase blood potassium levels, lower sodium levels, or interfere with kidney function in some people. Blood results are closely monitored throughout the study and if any of these problems are detected, participants are taken off the medication. These problems almost always disappear on stopping the medication. The blood tests may cause some minor discomfort. Although participants are

unlikely to benefit directly by taking part, those who receive the spironolactone might improve your muscle function and exercise capacity, making them feel stronger.

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?
October 2008 to April 2011

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
Section of Ageing & Health
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DD1 9SY

Additional identifiers

EudraCT/CTIS number
2008-002373-12

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CZB/4/635

Study information

Scientific Title
Effect of spironolactone on exercise capacity in older people without heart failure: a double-blind placebo-controlled trial

Study objectives

Inhibition of the renin angiotensin aldosterone system with spironolactone will improve exercise capacity in older people without heart failure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Committee of Medical Research Ethics, 06/08/2008, ref: 08/S1402/34

Study design
Double-blind randomised placebo-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
Decline in physical function with age

Interventions
Spironolactone 25 mg once daily or placebo once daily for a period of 20 weeks.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Change in six minute walking distance over 20 weeks from baseline

Secondary outcome measures
Change in the following from baseline to 20 weeks:
1. Time taken to perform the timed get up and go test
2. EuroQol 5D (-0.59 to 1.0) and Visual Analogue Scale (0 - 100)

3. Functional Limitation Profile Scale
4. Hospital Anxiety and Depression Scale (anxiety 0 - 21; depression 0 - 21)
5. Incremental shuttle walk test (time and distance)

Overall study start date
01/10/2008

Completion date
01/04/2011

Eligibility

Key inclusion criteria
1. Aged 65 years and over, either sex
2. Self-reported problems with activities of daily living

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
120

Key exclusion criteria
1. A clinical diagnosis of symptomatic heart failure according to the Economic and Social Research Council (ESRC) criteria
2. Asymptomatic left ventricular systolic dysfunction
3. Already taking spironolactone
4. On angiotensin converting enzyme inhibitor or angiotensin receptor blocker
5. Systolic blood pressure less than 100 mmHg
6. Serum potassium greater than 5.0 mmol/l
7. Serum sodium less than 130 mmol/l
8. Creatinine greater than 200 umol/l
9. Estimated glomerular filtration rate (eGFR) less than 30 ml
10. Addison's disease
11. Previous reported intolerance of spironolactone
12. Cognitive impairment precluding informed consent
13. Wheelchair bound
14. Unwilling to participate

Date of first enrolment
01/11/2008

Date of final enrolment
01/11/2010

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
Research and Innovation Services
11 Perth Road
Dundee
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United Kingdom
DD1 4HN

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/4/635)

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 on request from Dr Catrina Forde (c.forde@dundee.ac.uk) 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

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2013		Yes	No
Basic results		24/10/2017	20/11/2017	No	No