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PreFACE Study: Preventing Falls with ACE (angiotensin-converting-enzyme) inhibitors

Submission date
17/06/2013

Recruitment status
No longer recruiting

Registration date
02/08/2013

Overall study status
Completed

Last Edited
09/08/2017

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Falls are common and a major cause of concern in older people. A proven treatment to reduce the risk of falls is exercise, but many older people are unable to undertake enough exercise and if the exercise is not regular or the person stops doing it, the beneficial effects are lost. The benefit of exercise is that it improves muscle strength and stamina. This study will look at a drug, called perindopril, commonly used to treat high blood pressure that may be of benefit in improving muscle function, stability and muscle tiredness in older people at risk of falls. People's stability, i.e. how much they tend to sway while standing, and their muscle strength are assessed before and after treatment with a 15-week course of the drug. If the drug does improve the patients stability and reduces their risk of falls it might be a useful and easy to prescribe therapy for people at risk of falls in future.

Who can participate?
Anyone aged over 65 years who has been assessed at a Medicine for the Elderly Falls clinic in the past 2 years in NHS Tayside, UK. They must have had at least one fall within the past 12 months.

What does the study involve?
Participants are randomly allocated into two groups. One group receives the drug and the other group receives a dummy medication to see if there is a difference in these measurements between the two groups at the end of treatment. Participants are asked to attend Ninewells hospital twice in a 16-20 week period. These visits last for about two hours. Blood pressure, balance and leg strength are measured. Participants are asked to give a blood sample for further tests and are given a diary to record any falls. The study nurse also visits participants at home four times during this 16-20 week period. These home visits take about 15 minutes. Blood pressure and some blood samples (5 ml, no more than a teaspoonful) are checked on two further occasions when the nurse visits participants at home to ensure that the medication agrees with them. On the other two home visits the nurse attends to give participants supplies of study drug. Some participants who consent to it have a test to measure the strength with which their leg responds to a magnetic impulse applied to the nerve in their groin.

What are possible benefits and risks of participating?
The trialists cannot promise the study will help individual participants but the information from

this study will help improve the treatment of older people. Those who receive the drug may additionally improve their muscle function and balance. The drug rarely 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. Standing on the balance platform with eyes closed or while reaching forward and sideways may make participants feel off balance. The optional test using the magnetic impulse on participants femoral nerve may feel unpleasant. They may experience a tingling feeling. It lasts only a second or two and many older people have found it tolerable. Testing leg strength may lead to mild pain in your muscles and joints.

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

When is the study starting and how long is it expected to run for?
August 2013 to January 2016

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

Who is the main contact?
Dr Deepa Sumukadas
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2013-001677-24

Protocol serial number
2012GR06

Study information

Scientific Title
Do ACE inhibitors reduce postural instability in older people? Towards a novel approach to falls prevention

Acronym
PreFACE study

Study objectives
Use of the ACE inhibitor, Perindopril, improves postural instability in older people. Postural instability is a phenotype of the risk of falls

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A Research Ethics Committee, 28/05/2013, ref: 13/SS/0086

Study design
Double-blind randomised placebo-controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Falls in the Elderly

Interventions

This is a randomised double-blind controlled trial where participants will be randomly assigned to either perindopril or a matched placebo (dummy) tablet. Following screening visit to check eligibility for the trial and to collect baseline data on leg strength, balance and safety measures participants will then be randomised to receive either 2mg of perindopril or placebo for 2 weeks. They will then have blood pressure checked, adverse events monitored and bloods checked to ensure there are no safety issues. Should all be well they will have their study medications increased to 4mg for the rest of the study period, a further 13 weeks. They therefore receive study medications for 15 weeks in total in this trial. At their final study visit their leg strength, balance and blood tests will be reassessed to determine if there are any changes from baseline.

During the study period they will be seen at home twice by a researcher who will check blood pressure and safety bloods. Should there be concerns with any possible side effects of the medication they will either have their study medication reduced to 2mg (if they previously tolerated that dose) or study medication will be stopped though they will be encouraged to attend for the planned 15 week end of trial visit.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Anterio-Posterior (AP) sway measured at baseline and 15 weeks

Key secondary outcome(s))
1 Static postural stability measures: change in mediolateral sway, average sway velocity and total sway area after 15 weeks
2. Dynamic postural stability: change in Limits of Stability (LOS) after 15 weeks
3. Quadriceps strength: change in sometric Quadriceps Maximum Voluntary Contraction strength (QMVC) after 15 weeks
4 Falls rates (this study is not powered to determine this accurately but such information will provide important safety information as well as providing preliminary data for powering a future study)
5. Magnetic femoral nerve stimulation (subset of participants who consent only):
5.1. Change in the greatest Twitch tension generated in the Quadriceps (TwQ) using magnetic femoral nerve stimulation after 15 weeks
5.2. Improvement in endurance and fatigue using repeated QMVC after 15 weeks

Completion date
31/01/2016

Eligibility

Key inclusion criteria

1. Aged 65 years or over
2. One or more self-reported falls in previous 12 months
3. Been assessed at a Medicine for the Elderly Falls clinic in previous 2 years
4. Able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Already taking ACE inhibitor (ACEi) or Angiotensin Renal Blocker (ARB)
2. Contraindication to ACE inhibitor use [previous intolerance; significant aortic outflow obstruction (peak gradient >30mmHg) serum potassium >5.0mmol/l; eGFR<30ml/hr; serum creatinine >170umol/l]
3. Patients who have stopped ACEi or ARB after specialist falls assessment in the last 6 months
4. Clinical diagnosis of heart failure or asymptomatic left ventricular systolic dysfunction
5. Systolic BP>160mmHg or <100mmHg at screening visit
6. Wheelchair bound
7. Clinical diagnosis of Parkinsons disease
8. Current use of Nonsteroidal anti-inflammatory drugs (NSAIDs)
9. Patients who have participated in any other clinical drug trial within the previous 30 days will be excluded
10. Intolerance to lactose
11. Cognitive impairment precluding informed consent

Date of first enrolment
01/09/2013

Date of final enrolment
01/09/2015

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre

Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee/NHS Tayside (UK)

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (Ref CZH/4/856)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available upon request from Dr Miles Witham (m.witham@dundee.ac.uk). Anonymised Individual participant data on all those randomised will be made available to bona fide researchers for non-commercial use, subject to sight of an analysis plan and subject to appropriate data sharing agreements and approval from the trial Sponsor.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2018		Yes	No
Basic results		03/08/2017	09/08/2017	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes