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Do abnormalities in the control of brain blood flow account for dizziness on standing or after meals in older people?

Submission date
16/02/2012

Recruitment status
No longer recruiting

Registration date
19/03/2012

Overall study status
Completed

Last Edited
13/12/2017

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Orthostatic hypotension is where there is a large fall in blood pressure when a person stands from a lying position. Post-prandial hypotension is where a fall in blood pressure occurs within 2 hours of starting a meal. Both are common in older people. Previous studies have suggested that both these conditions can affect up to two thirds of those over 65 years of age. Both conditions can produce symptoms such as dizziness which can lead to health problems such as falls and hip fractures. Therefore these conditions have a tremendous impact on confidence and independence in older people. It has also been suggested by previous studies that death rates are higher. However, not all patients with a fall in blood pressure with standing or after meals have symptoms such as dizziness or light-headedness. On the other hand, some patients report symptoms suggestive of these conditions but do not have a significant fall in blood pressure. Cerebral autoregulation refers to how the body normally maintains a good blood flow within the circulation of the brain despite brief changes in blood pressure e.g. standing from a lying position. The stiffness or hardening of the arteries with age may also have an impact on cerebral autoregulation. There has been no investigation into why some patients who have orthostatic hypotension or post-prandial hypotension have symptoms and others do not. It may be that some people are less able to adapt to changes in blood pressure because of an underlying problem in cerebral autoregulation or increased hardening of arteries. Some patients have both conditions, but there has been little study into whether or not artery stiffness or maintenance of blood flow to the brain is the underlying problem in one or both conditions. The aim of this study is to investigate whether there is impairment in brain blood flow control (cerebral autoregulation) in orthostatic hypotension and post-prandial hypotension and whether this influences the presence or absence of symptoms.

Who can participate?
Anyone who can give informed consent and whom is over the age of 60 years of age can take part. They should not have atrial fibrillation (a condition where the heart beats very irregularly) or be on medication to slow the heart beat down as this can affect tests. This includes drugs such as atenolol and digoxin. Participants should be reasonably mobile as the study involves being tilted on a special bed.

What does the study involve?
Patients and volunteers (e.g. relatives) recruited to the study are divided into four groups for the orthostatic hypotension study and two groups for the post-prandial study based on whether they have a history suggestive of post-prandial hypotension.
The orthostatic hypotension study groups are as follows:
1. No orthostatic hypotension without symptoms
2. No orthostatic hypotension with symptoms
3. Orthostatic hypotension without symptoms
4. Orthostatic hypotension with symptoms
The post-prandial hypotension study groups are as follows:
1. No postprandial hypotension
2. Post-prandial hypotension
On the day of the test participants have their height and weight measured, followed by a basic clinical examination of the heart, lungs and the nervous system. Basic tests of heart rate and blood pressure response to standing, deep breathing, valsalva (blowing into a syringe) and handgrip are undertaken. Arterial stiffness is estimated using the time it takes for a pulse to travel the distance between the carotid artery in the neck and the femoral artery at the top of the leg. Changes in blood flow in the brain are measured using an ultrasound probe over the surface of the skull (transcranial Doppler) in a lying position and nearly standing position (i.e. a tilted position using a special bed). This is for a maximum of 30 minutes for the orthostatic hypotension study and 60 minutes for the post-prandial hypotension study. Those who feel light-headed are returned to a lying position immediately. Capillary blood sugar is checked by gently pricking the finger with a needle. This is only done once for the orthostatic hypotension study, but is done three times on each of the two days for the post-prandial study. For those taking part in the post-prandial study, participants are randomly allocated to drink Lucozade (containing glucose) or a sparkling water and sugar-free orange squash on two separate dates, whilst monitoring brain blood flow, blood pressure and heart rate changes. Observation between these groups for these parameters are looked at in the lying and nearly standing positions (tilted position) and analysed.

What are the possible benefits and risks of participating?
This study will provide information as to whether there is poor adaptation in the blood circulation in patients with orthostatic hypotension and post-prandial hypotension. The measurements will be compared to people with no orthostatic hypotension with or without symptoms. This will allow the targeting of treatments for this condition to improve quality of life for older people and reduce associated complications including falls and fractures. The main risk of taking part is provocation of symptoms if participants have a history of this. There is slight discomfort when a finger-prick blood sample is taken.

Where is the study run from?
The study is being carried out at the Norfolk & Norwich University Hospital site, but as part of the University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
Recruitment for the study began in February 2011 and shall continue until March 2013.

Who is funding the study?
Dunhill Medical Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9951

Study information

Scientific Title
Do abnormalities in dynamic cerebral autoregulation underlie the pathophysiology of the common causes of syncope in older people?

Study objectives
Part 1 - To investigate if differences in dynamic cerebral autoregulation are related to the symptoms of orthostatic hypotension in patients with and without a postural blood pressure (BP) fall
Part 2 - To investigate if:
2.1. Cerebral autoregulation is impaired in patients with post-prandial hypotension, and
2.2. If it is impaired to investigate if this relates to symptoms

The primary methodology will be using transcranial doppler ultrasound and other parameters to calculate the autoregulatory index. For Part 1 (Orthostatic hypotension) 80 participants will be observed during head up tilt whilst undergoing transcranial doppler ultrasound. For Part 2 (Post-

prandial hypotension) 40 participants shall undergo head up tilt and also receive an oral beverage (glucose and placebo on seperate attendances) in a randomised double-blind cross-over fashion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Norfolk Research Ethics Committee, 30/09/2010, ref: 10/H0310/46

Study design
Interventional double-blind randomised controlled and observational study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Syncope

Interventions
Participants shall have height, weight, medical history taken with a basic examination of the cardiovascular, respiratory and neurological system. Orthostatic grading score shall be obtained by answering a questionnaire. Autonomic function tests, Pulse Wave Velocity and Augmentation Index shall be measured at baseline.

Changes in cerebral blood flow velocities shall be measured using an transcranial Doppler ultrasound in a supine position and then with a 70 degree tilt. This will be for a maximum of 30 minutes for the orthostatic hypotension study and 60 minutes for the post-prandial hypotension study. Those who develop symptoms will be returned to a lying position immediately. Cerebral blood velocity, blood pressure and heart rate shall be simultaneously recorded.

A baseline capillary blood glucose shall be taken. Once for the orthostatic hypotension study, and at baseline, 30minutes and 60 minutes for the post-prandial study.

For those taking part in the post-prandial study, participants will be randomly allocated to drink Lucozade (containing glucose) or a sparkling water and sugar free orange squash on two separate dates within a 2 week period .

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Autoregulatory index for baseline, at 1 and 3 minute of tilt and the last 3 and 1 minute of tilt, the duration of which is dependent on the presence or absence of symptoms

Secondary outcome measures
1. Arterial stiffness
2. Baroreceptor sensitivity

Overall study start date
15/02/2011

Completion date
30/09/2013

Eligibility

Key inclusion criteria
Age >= 60 years, male or female

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria
1. Known autonomic neuropathy
2. Irregular heart rhythm such as atrial fibrillation
3. On drugs known to affect autonomic function
4. Uncontrolled high blood pressure
5. Stroke
6. Known carotid artery stenosis
7. Severe cognitive impairment
8. Severe physical impairment

Date of first enrolment
15/02/2011

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
University of East Anglia (UK)

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School of Medicine
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Sponsor type
University/education

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
Dunhill Medical Trust (UK)

Alternative Name(s)
The Dunhill Medical Trust, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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

IPD sharing plan summary
Not provided at time of registration