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Modified Valsalva Effectivness in Re-entrant Tachycardias (REVERT) study

Submission date 12/02/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/02/2013	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 01/09/2015	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Supraventricular tachycardia (SVT) is a heart problem that causes the heart to beat very quickly, affecting thousands of people. Attacks are unpleasant but not usually dangerous. When patients come to hospital with SVT, they can help to get their heart beat back to normal by doing a Valsalva Manoeuvre (VM). This is a strain while blowing, just like when trying to blow up a balloon. Often the VM does not work, however, and the patient is then usually given a strong medicine called adenosine. This has to be given into a vein and often makes people feel really unwell. Although this only lasts a few seconds, patients find it very unpleasant and some even say it makes them feel like they are about to die. Changing the way the VM is done might make it better at stopping the SVT. It is normally done with the person sitting (standard VM). If it's done in the same position but the person is laid down with their legs lifted at the end (modified VM), it might work better. The aim of this study is to compare the two different ways of doing the VM, to see if one version works better than the other.

Who can participate?
You can take part if you are:
-18 years or older.
-Have been diagnosed with SVT
However, you cannot take part if any of the following apply to you:
-You dont give your consent to take part in the study.
-You are unwell or need urgent medical treatment for another reason apart from your SVT.
-You have, or your doctor thinks you might have, another heart condition.
-There is any reason why you cant do a VM.
-There is any reason why you cant have your legs lifted.
-You are in the third trimester of pregnancy.
-You have already taken part in the study.

What does the study involve?
If you agree to take part, you will be asked to sign a consent form. The doctor will then open a sealed envelope containing a card which allocates you at random (like a flip of a coin) to one of the two positions. You will not be able to choose which VM you try, nor will your doctor.
For the manoeuvre itself, you will be asked to blow into a single-use tube, attached to a pressure

meter, for 15 seconds. You will be told how hard to blow and when to stop. You will then either remain sitting up or be laid down with your legs lifted up by the doctor or nurse for 15 seconds, before being sat up again.
If the first attempt does not slow your heart down, you will be asked to repeat the strain as it sometimes works the second time around. After this, we will record a heart tracing (ECG), and that is the end of the study. If you need further treatment, this will continue entirely as normal. Details of any further treatment given to you will be recorded for study purposes.

What are the possible benefits of taking part?
If you take part in the study, your heartbeat might return to normal without the need for drug treatment. This could also happen if you do not take part in the study. The results of the study will help to provide more information about the treatment of SVT, which may benefit other people with SVT around the world.

Where is the study run from?
The study is being overseen by the Royal Devon and Exeter NHS Foundation Trust. The study is taking place in the Emergency Department of the following 9 hospital Trusts:
-Wonford Hospital (Royal Devon and Exeter NHS Foundation Trust)
-Treliske Hospital (Royal Cornwall Hospital Trust)
-Derriford Hospital (Plymouth Hospitals NHS Trust)
-Torbay Hospital (South Devon Healthcare Trust)
-Musgrove Park Hospital (Taunton and Somerset NHS Foundation Trust)
-Frenchay Hospital (North Bristol NHS Trust)
-Bristol Royal Infirmary (University Hospitals Bristol NHS Foundation Trust)
-Royal United Hospital (Royal United Hospital Bath NHS Trust)
-Worcestershire Royal Hospital (Worcestershire Acute NHS Foundation Trust)

When is the study starting and how long is it expected to run for?
The study started recruiting in January 2013. Recruitment is expected to continue until December 2014.

Who is funding the study?
The study has been funded by the NIHR Research for Patient Benefit scheme.

Who is the main study contact?
Corinna Phillips, Assistant Trial Manager
corinna.phillips@pms.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Jane Vickery

Contact details
N14, I T T C Building
1 Tamar Science Park Davy Road
Plymouth
United Kingdom

PL6 8BX
-
jane.vickery@pms.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13791

Study information

Scientific Title
Randomised Evaluation of Modified Valsalva Effectivness in Re-entrant Tachycardias (REVERT) study

Acronym
REVERT

Study objectives
Supraventricular tachycardia (SVT) is a heart problem that causes the heart to beat very quickly, affecting thousands of people. Attacks are unpleasant but not usually dangerous. When patients come to hospital with SVT, they can help to get their heart beat back to normal by doing a Valsalva Manoeuvre (VM). This is a strain while blowing, just like when trying to blow up a balloon. Often the VM does not work, however, and the patient is then usually given a strong medicine called adenosine. This has to be given into a vein and often makes people feel really unwell. Although this only lasts a few seconds, patients find it very unpleasant and some even say it makes them feel like they are about to die. Changing the way the VM is done might make it better at stopping the SVT. It is normally done with the person sitting (standard VM). If it's done in the same position but the person is laid down with their legs lifted at the end (modified VM), it might work better. We plan to do a trial to find out. In this trial, people with SVT who come to hospital (but are not too unwell) will be asked if they would like to take part. People who take part will be allocated at random to do either the standard or the modified VM and the doctors will then check if their hearts have gone back to normal with a heart tracing (ECG). After this, participants will be treated as usual with no more testing. If we find that one type of VM is more successful, we will let patients and doctors know which to use, to reduce the number of patients who need to have adenosine or other emergency treatments when they get this problem.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=13791

Ethics approval required
Old ethics approval format

Ethics approval(s)

South West Exeter Research Ethics Committee, First MREC approval date 20/11/2012, ref: 12 /SW/0281

Study design
Interventional randomised controlled study; Design type: Treatment

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Re-entrant Tachycardia

Interventions
Control - Standard VM, Normal Valsalva strain at 40mmHg for 15 seconds in a semi-recumbent position, remaining in this position for 60 seconds after strain before reviewing ECG for cardioversion.

Intervention - Modified VM, Normal Valsalva strain at 40mmHg for 15 seconds in a semi-recumbent position, then lying participant flat and raising legs for 15 seconds before returning participant to semi-recumbent position for a further 45 seconds, before reviewing ECG for cardioversion.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The presence of sinus rhythm post Valsalva as determined by a 12 lead ECG.; Timepoint(s): 1 minute post-Valsalva

Secondary outcome measures
1. Adverse events; Timepoint(s): From time of consent until discharge from emergency department (ED)
2. The need for hospital admission Timepoint(s): Post-Valsalva until discharge from ED.
3. Time spent in ED; Timepoint(s): From time of admission until discharge from ED.

4. Use of other emergency treatments for SVT in ED; Timepoint(s): Post-Valsalva until discharge from ED

Overall study start date
13/01/2013

Completion date
01/09/2014

Eligibility

Key inclusion criteria
1. Age 18 years and over
2. Stable male or female adult patients presenting to the Emergency Department with SVT (regular, narrow complex tachycardia with QRS duration <0.12ms on ECG)
3. Written informed consent to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 372

Key exclusion criteria
1. Unstable patient (BP < 90mmHg systolic or any indication for immediate drug or DC cardioversion)
2. Atrial fibrillation or atrial flutter on ECG
3. Suspected atrial flutter requiring a trial of adenosine
4. Severe hypertension (systolic BP >220mmHg or diastolic >120mmHg)
5. Any contraindication to or inability to performing a VM
6. Contraindication or inability to lay flat or lift legs
7. 3rd trimester pregnancy
8. Patients without capacity to provide written informed consent
9. Previous inclusion in the study

Date of first enrolment
13/01/2013

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
N14, I T T C Building
Plymouth
United Kingdom
PL6 8BX

Sponsor information

Organisation
Royal Devon and Exeter Foundation Trust (UK)

Sponsor details
Royal Devon & Exeter Hospital
Barrack Road
Exeter
England
United Kingdom
EX2 5DW

Sponsor type
Hospital/treatment centre

Website
http://www.rdehospital.nhs.uk/

ROR
https://ror.org/03085z545

Funder(s)

Funder type
Government

Funder Name

National Institute for Health Research (NIHR) - Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0211-24145

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/10/2015		Yes	No