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A study to determine whether introducing a Valsalva assist device into normal ambulance service care can reduce the number of patients with supraventricular tachycardia who need to be taken to hospital.

Submission date
26/11/2021

Recruitment status
No longer recruiting

Registration date
24/03/2022

Overall study status
Completed

Last Edited
15/08/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims

A common heart problem called supraventricular tachycardia (SVT) can cause the heart to suddenly start beating very quickly. This causes palpitations and makes patients feel frightened and unwell. People with an episode of SVT are often first seen by ambulance service staff. Ambulance service guidelines recommend a simple, safe, physical treatment called the 'Valsalva manoeuvre' (VM) to get the heart beat back to normal. This involves a strain whilst blowing (like trying to inflate a stiff balloon), often done by blowing into an empty syringe. If the manoeuvre is successful, patients feel immediately better, do not always need to be taken to hospital and can see their GP at another time to plan further care.

Unfortunately, the VM often doesn't work and so most patients are taken to hospital where they may need strong, unpleasant drugs to correct their heart beat. However, blowing into a simple, easy to use, safe and approved product, the Valsalva Assist Device (VAD), provided by ambulance staff, might help patients do a better VM and avoid emergency hospital admission and drug treatment. The device, which has its own instructions, can be given to patients to keep and use themselves in case the SVT happens again, instead of the syringe. Patients, who have helped us design and run this study, tell us they really value feeling better as soon as possible and avoiding going to hospital if not needed. The other benefits of not taking people to hospital are that the ambulance can go to other patients sooner and hospitals have fewer emergency patients to see, with more time and space for others.

We plan to introduce the device into normal ambulance service care, (in a controlled way), to see if this can reduce the number of SVT patients who are taken to hospital. Only patients who would normally be treated with a VM would be included and only routine, anonymous data collected. It is just the way in which the VM strain is being done that will change; the rest of the patient's care will be the same as normal. However, we will also give patients written information about their condition and details of the study including how to opt out of having their data used, after they have been treated, should they wish.

If our study shows a benefit to patients, the ambulance service could continue to use the device. We think the money saved by avoiding as few as 1 in 10 hospital transfers could pay for a VAD in all the service's ambulances within 7 months. Devices are easy to use, require very little training and could easily be taken up by services in other regions and countries to benefit more patients.

Who can participate?
We aim to include all adult patients aged 18 and over who have undergone a Valsalva manoeuvre to treat Supraventricular tachycardia, as recorded on the electronic patient clinical record (ePCR), during the study period, delivered by an ambulance clinician assigned to a participating ambulance station.

What does the study involve?
The aim is to determine whether routine ambulance service access to the VAD and its instructions, to treat adult patients with attacks of SVT can decrease the percentage of patients that are taken to hospital compared to current standard care.
Currently, the actions of ambulance clinicians attending a patient with SVT is variable. In an otherwise stable patient, they often attempt to treat the patient, usually with one or more attempts at a Valsalva Manoeuvre. This may or may not involve the use of an aid such as a syringe. If successful in returning the patient's heart rhythm back to normal, the decision may be made that the patient does not need transfer to hospital.
In routine treatment for SVT, the VM has a low rate of success for treating patients and often results in the need to use unpleasant intravenous treatments. Recent studies have shown that using a modified VM technique which includes patients having a controlled strain, e.g. like that you may experience with straining with a stool or during childbirth, can significantly improve the success in trying to return a patient's heart rhythm back to normal (cardioversion). Currently this strain can be generated by blowing on an empty syringe. However, studies have shown that the syringes can be unreliable in providing the right and consistent pressures to help with cardioversion.
This single-patient use Valsalva assist device (VAD), with its instructions for the correct duration and position of strain, could standardise how ambulance staff deliver treatment. The device should ensure that the correct pressure is achieved, while instructions written on the device should help to ensure its correct use.
Where ambulance stations have been opened for the study (supplied with the device), which will be done in phases across the region, patients will be provided with the device, blow into it and measurements taken to see if their rhythm has returned to normal. They will be left with the device and if they consent to be having their routine data used from the episode of SVT, will be included in the study.

What are the possible benefits and risks of participating?
The VM is a very safe standard intervention with no evidence of harm in previous large studies and there is no reason to believe the trial intervention will pose any additional risks or significant delay in the patient's treatment.
The benefits include treating patients closer to home and increased patient satisfaction with appropriate on scene ambulance treatment. A more effected pre-hospital VM would reduce the time of the patients' symptoms and may avoid the need for them to go to hospital. The device will also be left with patients, with instructions to allow them to attempt to return their heart rhythm back to normal, in the first instance themselves, if they should have another SVT attack.

Where is the study run from?
The study will be conducted entirely within South Western Ambulance Service NHS Foundation

Trust (SWASFT), treating patients in the South West of England, UK. This ambulance service has established clinical guidelines supporting the use of a modified VM, and not taking patients to hospital unnecessarily if they have been successfully treated for SVT.

When is the study starting and how long is it expected to run for?
January 2022 to June 2024

Who is funding the study?
National Institute for Health Research (NIHR), Research for Patient Benefit (RfPB) programme (UK)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
287604

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR202185, CPMS 52099

Study information

Scientific Title
Evaluation of Pre-hospital use of a Valsalva Assist Device (VAD) in the Emergency treatment of supraventricular tachycardia (SVT). A definitive stepped-wedge cluster randomised controlled trial [EVADE SVT]

Acronym
EVADE SVT

Study objectives
To determine whether routine access to the VAD will enable ambulance clinicians to provide a more effective Valsalva Manoeuvre (VM) and reduce the percentage of patients that are conveyed to hospital compared to the current standard VM which typically utilises blowing on a syringe to generate the VM strain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2022, South Central – Oxford C REC (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 104 8256; oxfordc.rec@hra.nhs.uk), ref: 22/SC/0032

Study design
Single-centre interventional stepped-wedge cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Emergency treatment of supraventricular tachycardia (SVT)

Interventions

The stepped wedge randomised introduction of a single-patient use Valsalva assist device (VAD) for the routine treatment of SVT by ambulance clinicians. This will be compared to current standard methods of delivering a Valsalva manoeuvre (VM) (typically blowing on a syringe) to treat SVT (control).

The VAD is a simple approved (CE marked) device that provides the recommended VM strain pressure (40 mmHg) resistance when blown into as part of the VM. The VAD is small and portable and is conveniently packaged with clear instructions on how to correctly perform the modified Valsalva Manoeuvre (VM) to attempt cardioversion during an SVT attack.

Control Arm:
Standard treatment as per SWASFT clinical guideline CG21 'Supraventricular Tachycardia (normally a Valsalva Manoeuvre using a standard 10 ml syringe to generate a 'strain')

Intervention Arm:
Valsalva Manoeuvre using the VAD with its instructions for use.

Current standard care and established clinical guidelines for the treatment of SVT (SWAFT Clinical Guideline CG21 'Supraventricular Tachycardia) which recommends treatment with a 10ml syringe will be followed until the introduction of the VAD according to the randomisation schedule. After the introduction, the device will be routinely available to all clinicians in the cluster for use alongside updated guidelines enabling VAD use. Only the VM strain method will change and care will not be changed in any other way. Reminders to access the Valsalva pouch will be placed with the ECG leads (accessed when assessing SVT patients) in ambulances from the commencement of the trial. However, this is a pragmatic trial and like other equipment introduced into practice, clinicians cannot be mandated to use the VAD, once introduced. Its use will be recorded as a process variable and so results will reflect the usability, acceptability and real-world effects of device introduction.

Potential study participants should undergo the standard clinical assessment of SVT patients attended by ambulance. This typically includes medical history, recording of routine initial observations of pulse, blood pressure, respiratory rate, oxygen saturation and the recording of a 12-lead ECG. Baseline data will be routinely entered into the electronic Patient Clinical Record (ePCR) system and accessed later. The screening of eligibility for VM treatment and the conduct of the VM and all other aspects of clinical care will be entirely governed by SWASFT clinical guidelines, interpreted and followed at the discretion of the treating clinician.

Ambulance station clusters will be formed from 93 SWASFT ambulance stations. After merging very small and closely located stations, whilst maintaining the largest possible number of similar-sized clusters, 80 (mostly single-station) ambulance station clusters have been identified. Data on activity and general conveyance rates for each cluster have been collected to inform the sample size and will be used to stratify randomisation. Clinicians working from these stations use equipment bags strictly belonging to and stocked by that station. Our proposed stepped-wedge design comprises 5 stages, each stage lasting 4 months. In the first stage, none of the station clusters will have access to the VAD. The clusters will then be randomly allocated by computer-generated sequences (stratified by cluster size and location) to include VADs with their equipment bags, in one of the four remaining stages, so that 20 clusters and their clinicians receive access to the VAD for the first time in each stage. Randomisation will be performed by an independent statistician otherwise unconnected with the trial.

All stations in a cluster randomised to VAD use, will initiate availability of the VAD on the same day, co-ordinated by SWASFT supply logistics and appointed local station 'champions' (as used in

the feasibility trial). These processes will be overseen by CTU to ensure protocol compliance as far as possible. Stations will be notified of activation with sufficient time to enable Valsalva pouches to be changed and all station clinicians to be notified. No other individuals outside the logistics supply chain and the station clinicians will be made aware of the randomisation.

The planned trial period is from 1st January 2022 to 30th June 2024. We propose to begin cluster activation in 5 stages, beginning 1st June 2022, at which point patient recruitment can begin. The activation period and open-for-recruitment period will last 20 months. Ambulance service notes follow-up will be at 30 days for safety data follow-up and 3 months post-manoeuvre to record any further episodes of SVT.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
Valsalva Assist Device (Valsa-Valve)

Primary outcome(s)
Conveyance of patient to hospital as recorded in the Electronic Patient Care Record (ePCR)

Key secondary outcome(s))
As recorded in the Electronic Patient Care Record (ePCR):
1. The number of VM attempts used
2. Confirmation of Valsalva strain method used
3. Any evidence of postural modification to the VM
4. Cardioversion (return to normal heart rhythm) as recorded by the treating ambulance clinician (including spontaneous cardioversion)
5. Total time of the ambulance episode
6. Further ambulance attendance for SVT including subsequent conveyance to hospital (to rule out the possibility that treatment simply postpones attendance to hospital) for the duration of the trial and 3 months thereafter.
7. Compliance with SWASFT conveyance guidelines
8. Ambulance attendance for any reason within 30 days of index presentation (safety monitoring)
9. Demographic data to ensure the two trial arms are similar with respect to participant characteristics and that all patient groups, commensurate with the local population demographic, have the opportunity to take part in the research
10. Estimate of diagnostic appropriateness (through the retrospective expert reading of available, interpretable pre-Valsalva ECG traces as recorded in the ePCR). Traces with severe interference will be excluded and all other Traces will be classified
as: Rhythm Eligible for a VM (eg re-entrant SVT, undetermined SVT) or Rhythm Ineligible for VM (eg atrial fibrillation, atrial flutter, sinus tachycardia)
11. Quality of life questionnaire (EQ5D) data from the optional online link, where available

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Adult patients (above 17 years)
2. Record of a Valsalva manoeuvre for presumed supraventricular tachycardia having been delivered by an ambulance clinician asigned to an ambulance station cluster.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
17 years

Sex
All

Total final enrolment
865

Key exclusion criteria
1. Subsequent withdrawal of patient consent to use data
2. Data from participants who are prisoners at the time of treatment
3. Patients with permanent lack of capacity as recorded by the treating clinician
4. Patients solely treated by a SWASFT resource not from one of the included ambulance station clusters e.g. Air Ambulance, Hazardous Area Response Team, Tiverton Minor Injuries Unit, British Association for Immediate Care (BASICS) Doctor
5. Data from patients previously included in the study will be excluded from the primary analysis but will be used in other secondary analyses
6. Patients who have previously registered with the National Data Opt-out service

Date of first enrolment
01/07/2022

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

South Western Ambulance Service NHS Foundation Trust
Abbey Court
Eagle Way
Exeter
United Kingdom
EX2 7HY

Sponsor information

Organisation
South Western Ambulance Service NHS Foundation Trust

ROR
https://ror.org/009dhvf97

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available REDCap database held by the collaborating CTU. Routinely collected, non-identifiable patient data will be extracted from the attending ambulance clinician-populated

electronic patient care record (ePCR) and uploaded by the study Research Paramedic to the secure and non-publically available study database following quality, eligibility and completeness checks. The consent model used in this study is an opt-out model. Patients will be provided with a patient information sheet explaining the use of their routine data and how to opt-out from inclusion in the study at any point. They will also be provided with the contact details for the Study Research Paramedic should they have any questions at any point post intervention.

IPD sharing plan summary

Stored in non-publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/08/2025	15/08/2025	Yes	No
Protocol article		08/06/2023	09/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes