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Clinical trial of a novel tourniquet (Vacuderm tourniquet) which aims to aid further filling of veins through a pumping mechanism

Submission date
16/11/2016

Recruitment status
No longer recruiting

Registration date
27/03/2017

Overall study status
Completed

Last Edited
07/05/2021

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Cannulation is the procedure in which a patient's skin is punctured with a needle to allow insertion of a temporary plastic tube into a vein. It can be performed by doctors, phlebotomists, trained nurses and trained health care assistants. Venous cannulation is performed on about 80% of patients admitted into hospital in order to administer fluids, drugs, blood or blood products. Cannulation is the most commonly performed invasive medical procedure in hospitalised patients and is frequently life-saving. The NHS in England and Wales currently use about 26 million cannulae per year. However, the procedure is not always successful and the failure rate can range from 15 to 30%. In patients who have had multiple previous cannulations the failure rate can much higher particularly, for example, in those who have received chemotherapy before. Each attempt is painful and can cause bruising, with the obvious added distress to the patient. The Vacuderm tourniquet is a device designed to assist with difficult cannulation and blood-taking procedures through the use of a dome feature which can be used to "pump" blood into the veins, making them larger and therefore easier to access. The aim of this study is to investigate whether the use of Vacuderm can reduce the failure rate of cannulation.

Who can participate?
Emergency department patients aged 18 and over who require venous cannulation and have had a failed first attempt at cannulation on the current occasion

What does the study involve?
Participants are randomly allocated to undergo a second attempt at cannulation using either the Vacuderm tourniquet or the conventional standard tourniquet. The success rate of cannulation, safety, user acceptability and patient satisfaction are assessed in both groups.

What are the possible benefits and risks of participating?
Cannulation failure is often distressing to patients. There is a chance of failure with every

cannulation attempt, leading to patient discomfort and other side effects. Vacuderm may benefit the patients by making cannulation easier. The risk of use of the Vacuderm is not considered greater than that of using a standard tourniquet or blood pressure cuff.

Where is the study run from?
Royal Derby Hospital (UK)

When is the study starting and how long is it expected to run for?
January to April 2017

Who is funding the study?
Olberon Ltd (UK)

Who is the main contact?
Kara Baron
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
olb/vac/001

Study information

Scientific Title

Randomised control trial of a novel tourniquet (Vacuderm tourniquet) which aims to aid further filling of veins through a pumping mechanism

Study objectives
Does the use of the Vacuderm tourniquet significantly improve the success rate of venous cannulation when compared to the use of a conventional tourniquet?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre randomised control 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Diffficult venous access - cannulation procedure

Interventions
Participants are randomised to undergo cannulation using either the Vacuderm tourniquet or the control, which is the conventional standard tourniquet. Participants will be recruited on to the trial if they have already had an attempted cannulation procedure performed on the current occasion and this has failed; the second attempt will be performed after the participant has been randomised.

Intervention Type
Device

Primary outcome measure
Success rate of venous cannulation, measured by recording the tourniquet (Vacuderm or control tourniquet) used and whether the cannulation attempt was successful

Secondary outcome measures

1. Safety: an inspection of the tourniquet site will be carried out after 30 minutes and any adverse events will be recorded in the case report form
2. User acceptability, recorded on the case report form, whether cannulation was successful or not
3. Patient/participant satisfaction, measured using a visual analogue scale (VAS)
4. Cannula size, recorded on the case report form for the first failed attempt at cannulation and the cannula size will again be recorded after randomisation for the second attempt
5. Provisional diagnosis, recorded by the trained delegate on the case report form
6. Potassium levels - haemolysis, recorded by the trained delegate on the case report form
All measured at a single timepoint

Overall study start date
09/01/2017

Completion date
28/04/2017

Eligibility

Key inclusion criteria
1. Emergency department patients aged 18 and over
2. Able to provide informed consent
3. Requiring venous cannulation
4. Has had a first attempt failed cannulation within the emergency department during this attendance
5. The patient has an appropriate site for cannulation in the upper limbs in the opinion of the investigator

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. In the opinion of the investigator the patient has a contra-indication to use of tourniquet or blood pressure cuff (for example a low platelet count causing bruising)
2. Critically ill patients who need emergent IV access
3. Small cannula being used on patient – ie 22 gauge (blue) and smaller

Date of first enrolment

09/01/2017

Date of final enrolment
28/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
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DE22 3NE

Sponsor information

Organisation
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Sponsor type
Industry

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ROR
https://ror.org/01rjdjc72

Funder(s)

Funder type
Industry

Funder Name
Olberon Ltd

Results and Publications

Publication and dissemination plan
Results will be made available once statistical analysis has been performed and written up.

Intention to publish date
01/07/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Graham Johnson (graham.johnson4@nhs.net).

IPD sharing plan summary
Available on request