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Tourniquet and ultrasound radial artery cannulation

Submission date	Recruitment status	[_] Prospectively registered
01/12/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/12/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/07/2018	Surgery	

Plain English summary of protocol

Background and study aims
Cannulation is a commonly used medical procedure where a small tube is inserted into a vein or artery for access. Radial artery (the main artery in the forwarm) cannulation is used routinely in clinical settings for many purposes, such as accurate monitoring of beat-to-beat blood pressure, repeated multiple blood sampling and some surgical procedures. The radial artery is small, and so can be very difficult to cannulate however. Multiple attempts to cannulate can be risky and lead to risk and complications such as temporarily blocking the artery (occlusion), blood clots and bleeding. It is therefore important to find an easy, convenient and quick method for accessing the radial artery. In recent years, ultrasound (US) devices have been used to visualise blood vessels in order to access them with a cannula. Additionally use of a tourniquet (tight band to cut of blood supply) can also help improve cannulation success rates. The aim of this study is to find our whether using a tourniquet can improve the success rate of radial artery cannulation when using ultrasound.

Who can participate?
Adults undergoing major non-emergency surgery who require continuous beat-to-beat blood pressure monitoring throughout their operation.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have a tourniquet tied as tightly as possible around the arm. Those in the second group have a tourniquet loosely tied on the far-end of the wrist. Following this, participants in both groups are cannulated using an ultrasound probe to visualise the artery. The time taken to successfully place the cannula is recorded for participants in both groups.

What are the possible benefits and risks of participating?
Participants could benefit from improved success rates of cannulation and a shorter cannulation time. There are no notable risks of participating other than the general risks associated with cannulation, such as pain or bruising.

Where is the study run from?
Shanghai Jiaotong University Affiliated Shanghai No.6 People’s Hospital (China)

When is the study starting and how long is it expected to run for?
March 2014 to December 2016

Who is funding the study?
Investigator initiated and funded (China)

Who is the main contact?
Ms Quanhong Zhou

Contact information

Type(s)
Scientific

Contact name
Miss Quanhong Zhou

Contact details
600 Yishan Road
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200233

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2014-19

Study information

Scientific Title
When tourniquet meets ultrasound for radial artery cannulation: a way to improve the quality of monitoring

Study objectives
Distal tightened tourniquet may facilitate ultrasound guided radial artery cannulation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Shanghai Jiaotong University-affiliated Shanghai No.6 People’s Hospital, 26/03/2014, ref: 2014-19

Study design
Randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Radial artery cannulation

Interventions
Participants are randomly allocated to one of two groups using the sealed envelope technique. In both groups, the tourniquet is placed distally to the ulnar styloid process.

Group 1: The tourniquet is tied as tightly as possible

Group 2: The tourniquet is loosely tied on the far-end of the wrist

Following application of the tourniquet, an assistant sterilizes the forearm skin and put a sheet with hole at the insertion site to cover the tourniquet. Doctor could not see the tourniquet when performing the cannulation. An ultrasound probe is used to search for the optimal site for needle insertion and the needle is inserted at the center of the probe. If blood flushes out, the sheath of the needle is inserted and the needle taken out. The sheath is then connected to monitor (CARESCAPE, GE) via a pressure sensor (Combitrans Arterial Monitoring Kit B/BRAUN). A successful cannulation is announced when an arterial wave is shown on the monitor. The time from needle insertion to the successful wave shown is defined as radial artery cannulation time.

Intervention Type
Procedure/Surgery

Primary outcome measure
First-attempt success rate is measured by how many patients had first-attempt success out of the whole population in his/her group (n=120) at the end of the study.

Secondary outcome measures
1. Number of attempts is counted and verified using ultrasound scanning
2. Failure rate is measured by how many patients had failed out of the whole population in his /her group (n=120) at the end of the study
3. Time used for cannulation is measured using stopwatch by assistant at the process of

cannulation
4. Frequency of posterior wall technique used is measured by how many patients had posterior wall technique out of the whole population in his/her group (n=120) at the end of the study

Overall study start date
01/03/2014

Completion date
01/12/2016

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Undergoing elective major surgery
3. Assumed to require continuous blood pressure monitor during their operation

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Key exclusion criteria
1. Patients with abnormal Allen test
2. Peripheral vascular diseases
3. Scars at the forearm i.e. insertion site

Date of first enrolment
07/04/2014

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
China

Christmas Island

Study participating centre
Shanghai Jiaotong University Affiliated Shanghai No.6 People's Hospital
600 Yishan Road
Shanghai
China
200233

Sponsor information

Organisation
Shanghai Jiaotong University affiliated Shanghai Sixth People's hospital

Sponsor details
600 Yishan Road
Shanghai
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200233

Sponsor type
Hospital/treatment centre

Website
www.6thhosp.com

ROR
https://ror.org/049zrh188

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a low-medium-impact peer reviewed journal.

Intention to publish date

01/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Quanhong Zhou, zhouanny@hotmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018		Yes	No