# Tourniquet and ultrasound radial artery cannulation

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
01/12/2016		☐ Protocol		
<b>Registration date</b> 05/12/2016	Overall study status Completed	Statistical analysis plan		
		[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 Shanghai China 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 China 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

#### 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