

Cannulation of the radial artery with three dimensional biplanar versus conventional two dimensional ultrasound guidance

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Compare performance of radial artery catheterization using three dimensional biplanar ultrasound guidance versus conventional two dimensional US

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON50629

Source

ToetsingOnline

Brief title

CARATUS

Condition

- Vascular therapeutic procedures

Synonym

artery of the wrist, radial artery

Research involving

Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: investigator initiated; geen extra financiering

nodig

Intervention

Keyword: Arterial catheterization, Three dimensional ultrasound, Ultrasound guidance

Outcome measures

Primary outcome

First pass success, that is needle entry in the radial artery within one skin break and no needle redirection, confirmed by arterial wave pressure form on the monitor

Secondary outcome

scan time, needling time, procedure time, number of skin punctures, number of needle redirections, complications including posterior wall puncture, and hematoma, needle visibility, operator satisfaction

Study description

Background summary

Arterial cannulation for continuous invasive blood pressure monitoring and blood sampling is a standard procedure for patients undergoing major abdominal or cardiothoracic surgery. Traditionally performed by digital palpation, ultrasound (US) is increasingly used for this procedure. However, US guidance marginally increases success rates for this procedure. As US techniques can be performed in short or long axis, both approaches have their shortcomings. Using three dimensional biplanar US, both short and long axis views can be displayed simultaneously. We hypothesize the additional information of the anatomical site will improve radial artery cannulation success rate.

Study objective

Compare performance of radial artery catheterization using three dimensional biplanar ultrasound guidance versus conventional two dimensional US

Study design

Before/after

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Arterial cannulation is a standard procedure for cardiothoracic surgery, no additional invasive procedures will be performed. Serious complications of this technique are rare, but local hematoma does occur more frequently. Also, the success rate despite ultrasound is not 100%, and multiple punctures are related to the more frequent occurrence of complications. The intervention aims to further optimize this technique and potentially decrease complications. Based on our own experience, we expect the new technique to cause less tissue trauma and hematoma. Therefore, patients participating in this study are not exposed to extra risks other than that of the conventional radial artery cannulation procedure

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- adult patients >18 years
- scheduled for cardiothoracic surgery
- written informed consent

Exclusion criteria

- Emergency surgery
- Unable to obtain informed consent
- Vascular access via alternative approach / anatomical variations hindering radial artery catheterization

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-2021
Enrollment:	160
Type:	Actual

Medical products/devices used

Generic name:	3D Ultrasound
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Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 24-09-2021

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27798

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL78704.100.21
OMON	NL-OMON27798