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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27798

Source
Nationaal Trial Register

Brief title
CARATUS

Health condition

cardiac disease

Sponsors and support

Primary sponsor: n/a
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

first pass success rate

Secondary outcome

scan time, needling time, procedure time, number of attempts, number of needle redirection, operator satisfaction, needle visibility, complications

Study description

Background summary

Rationale: 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.

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

Study design: Prospective randomized controlled trial

Study population: Adult patients >18 years, requiring scheduled cardiothoracic surgery for which radial artery catheterization is required

Intervention: Radial artery cannulation using three dimensional biplanar US guidance

Main study parameters/endpoints: First pass success rate, 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 objective

3D guided arterial cannulation increases first pass success rate and decreases punctures

Study design

February 2022: analysis of primary and secondary endpoints,The primary endpoint, first pass success, will be compared between the group where 3D US is used, compared to the 2D US group, using a chi square test. Regarding secondary study parameters, for continuous variables, distribution of data will be assessed for normality. If a normal distribution is found, a parametric t-test will be used. If the data is not normally distributed, a mann whitney u test will be used. Categorical data will be analysed using a chi squared test. Fisher’s exact test

will be used for data with small sample sizes.

Contacts

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Eligibility criteria

Inclusion criteria

adult patient, elective cardiothoracic surgery requiring radial artery cannulation

Exclusion criteria

no informed consent, anatomical abnormalities at access site,or other site of arterial access

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2021
Enrollment:	160
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 50629
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9687
CCMO	NL78704.100.21
OMON	NL-OMON50629

Study results