Catheterization of the radial artery with fixated ultrasound transducer

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Primary Objective: Investigate whether fixation of the ultrasound probe, thereby freeing both hands for needling, improves performance of radial artery punctureSecondary Objective(s): Investigate whether fixation of the probe will lead to decreased...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43145

Source
ToetsingOnline

Brief title
CRAFT

Condition

- Other condition
- Vascular therapeutic procedures

Synonym
n/a

Health condition

diagnostiek

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: arterial catheterization, radial artery, ultrasound, vascular access

Outcome measures

Primary outcome

The main study endpoint will be the rate of successful first attempt for catheterization. An attempt is defined as a straight advancement of the needle until positioned in the artery. If the needle is withdrawn 5 mm or more and advanced again, this counts as a new attempt.

Secondary outcome

Secondary endpoints will be total time for completion of the procedure, for the digital palpation group this is the time from first palpation of the artery till placement of the catheter. In the US groups, this is the time from first contact of the US transducer with the subject*s skin until placement of the catheter.

Other recorded parameters will be total attempts needed to complete the procedure, total attempts per group, skin punctures, failures

Study description

Background summary

Arterial cannulation for continuous invasive blood pressure monitoring and blood sampling is a standard procedure for patients undergoing 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. A possible explanation is unintentional movement of the US probe during manipulation of the needle when targeting the artery. We hypothesize that by fixating the probe during puncture, by eliminating inadvertent displacement of the probe the US image will be more steady, thereby improving performance of the cannulation procedure.

Study objective

Primary Objective: Investigate whether fixation of the ultrasound probe, thereby freeing both hands for needling, improves performance of radial artery puncture

Secondary Objective(s): Investigate whether fixation of the probe will lead to decreased occurrence of (local) complications, e.g. hematoma

Study design

The study will be a prospective, randomized, non-blinded trial

Intervention

fixation of the ultrasound probe during radial artery catheterization

Study burden and risks

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. From our own experience, we expect the new technique to cause less tissue trauma and hematoma.

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

written informed consent
elective major abdominal or cardiothoracic surgery

Exclusion criteria

No informed consent
Emergency procedures
Pre-existing injury at the radial artery cannulation site (hematoma, infection, surgery e.g. radial artery harvesting)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-06-2016
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

No registrations found.

In other registers

Register	ID
CCMO	NL56971.100.16