3D Biplane vs conventional 2D ultrasound Guided Internal jugular VEin caNnulation in CardiotHoracic surgerY patients

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Compare 3D biplanar with conventional 2D short axis US guided internal jugular catheterization

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

Summary

ID

NL-OMON51094

Source
ToetsingOnline

Brief title
3D US jugularis / 3d Givenchy

Condition

- Cardiac therapeutic procedures

Synonym
great neck vein i.v., internal jugular vein catheterization

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: eigen initiatief ziekenhuis

Intervention

Keyword: 3d ultrasound, internal jugular vein, vascular access

Outcome measures

Primary outcome

First pass success rate

Secondary outcome

imaging time, procedure time, number of skin punctures, number of needle

redirections, complications including posterior wall puncture, needle

visibility, operator satisfaction

Study description

Background summary

Central venous catheterization through the jugular vein is a standard procedure for cardiothoracic surgical patients. Ultrasound (US) guidance is preferred and compared to traditional landmark approach decreases complications and increases success rate. Both long and short axis views are used for obtaining access, both with their own advantages and shortcomings. Complications have also not completely diminished with the use of US. We propose a new technique using 3D biplanar imaging, combining advantages from both long and short axis views in one image, enabling more successful procedures and a lower complication rate

Study objective

Compare 3D biplanar with conventional 2D short axis US guided internal jugular catheterization

Study design

Prospective randzomized controlled trial

Intervention

Central venous access with 3D biplanar US guidance

Study burden and risks

2D US guided internal jugular vein catheterization is a standard procedure in cardiac operating theatres and is a basic skill for cardiac anesthesiologists. The intervention aims to further optimize this technique and potentially decrease complications such as posterior wall punctures leading to carotid artery puncture. Therefore, patients participating in this study are not exposed to extra risks other than that of the traditional central venous access 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 scheduled for cardiothoracic surgery
age 18-85
written informed consent

Exclusion criteria

- Emergency surgery
- Unable to obtain informed consent
- Vascular access via alternative approach (subclavian vein)

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):	01-11-2021
Enrollment:	104
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	05-02-2021
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

No registrations found.

In other registers

Register	ID
CCMO	NL76278.100.20