Insertion of a central venous catheter through a tegaderm as a preventive measure against catheter colonization and infection

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Primary: Investigate if sterile transparent dressing pasted on the skin before CVC insertion reduces the contamination risk of the CVC.Secondary: Investigate if direct contamination has a clinical significance.Investigate what the mayor…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30053

Source
ToetsingOnline

Brief title
CEVEKAKOL 2

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
Catheter related infection; Infection due to central venous catheter

Research involving
Human

Sponsors and support

Primary sponsor: Anesthesiologie

Source(s) of monetary or material Support: Arrow International, Inc ,Maatschap anesthesiologie St. Antoniusziekenhuis

Intervention

Keyword: catheter related infection, central venous catheter, intensive care, nosocomial infection

Outcome measures

Primary outcome

Reduction of 50% of contamination in the intervention group

Secondary outcome

Determine what the percentage of direct contamination after CVC insertion.

Matching of the micro-organism on the skin of the patient; the blood culture;

the glove of the anesthesiologist and the surgeon with the micro-organism on

the catheter tip.

Reduction of catheter related infections (CRI) in the intervention group

compaired with the nonintervention group.

The percentage CRI in the group of patients who were directly contaminated

compaired with the percentage CRI in the group who were not directly

contaminated.

The percentage positive bloodcultures after induction of anesthesia.

Study description

Background summary

In intensive care (IC) medicin central venous catheters (CVC) are frequently used. CVC's are a potential risk for nosocomial infections. CVC's are thus a major cause of a serious complication on the ICU. These infections are associated with an overall attributable mortality, morbidity and attributable

costs.
A possible contamination source is direct contamination after insertion. Although the CVC is inserted under strikt sterile conditions the CVC can be contaminated directly during insertion. The skin is most likely the contamination source. The contamination chance could be reduced if the skin is covered with sterile transparent dressing. With this study we will investigate if application of a sterile transparent dressing on the skin before CVC insertion reduces the contamination risk.

Study objective

Primary:

Investigate if sterile transparent dressing pasted on the skin before CVC insertion reduces the contamination risk of the CVC.

Secondary:
Investigate if direct contamination has a clinical significance.
Investigate what the mayor contamination source is.
Investigate if sterile transparent dressing prevents catheter related infection (CRI).
Investigate what the relation is beween direct contamination and CRI
Investigate how often the bloodculture is positive after induction.

Study design

Single blind randomised study

Intervention

After randomisation a sterile transparent dressing will be applied on the skin of one group of the patients before the CVC is inserted.

Study burden and risks

The study implicates that next to the usual central venous catheter (CVC) one additional CVC will be inserted in the right internal jugular vene. Both CVC's will be placed under general aneasthesia, the extra CVC will be removed at the end of the operation. The patient will still be under general aneasthesia. Insertion of CVC in the internal jugular vene can be complicated by pneumothorax and perforation of the internal carotis artery. However the additive risk is negligible because the anaesthesiologist is aware of the exact location of the internal jugular vene.
Furthermore one extra blood culture (20 ml.) will be done postoperatively. Two extra bloodsamples will be taken (2 ml. a day).
Cutting of the CVC in situ can also be an additional risk factor. As well as

one of the thoracic surgeons as the manufacturer of the CVC have declaired that they approve with the study protocol.

Contacts

Public
Selecteer

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Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Cardiac surgery patients in whom the surgery indicates to open the right atrium after starting cardiac pulmonairy bypass

Exclusion criteria

Younger than 18 years

Endocarditis
proven bacterial infection

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2007
Enrollment:	600
Type:	Actual

Medical products/devices used

Generic name:	Sterile transparent dressing
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	13-12-2006
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	NL13186.100.06