

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Hepatobiliary neoplasms malignant and unspecified
<b>Study type</b>	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 compared with the nonintervention group.

The percentage CRI in the group of patients who were directly contaminated compared 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) medicine 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 between 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 aneesthesia, the extra CVC will be removed at the end of the operation. The patient will still be under general aneesthesia.

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 declared that they approve with the study protocol.

## Contacts

### Public

Selecteer

Koekoekslaan 1

3435 cm

NL

### Scientific

Selecteer

Koekoekslaan 1

3435 cm

NL

## 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 pulmonary 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