

Effects of the implementation of a specific Safety Checklist in cardiac surgery

Submission date 12/06/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/06/2018	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 14/06/2018	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Cardiac (heart) surgery has become a routine procedure with acceptable risks. However, there is still room for improvement, especially in elderly patients with multiple comorbidities (illnesses). Each of these conditions may require special measures during or shortly after the operation. In these complex situations checklists may help to structure and improve communication between different caregivers. A specific cardiac surgery safety checklist was developed in one hospital (Isala) and then implemented in six other Dutch cardiac centers. This safety checklist focuses on pre-operative known risk factors in combination with a trans-esophageal echo (an ultrasound scan of the heart) that is performed just after induction of anesthesia.

Who can participate?

Adult cardiac surgery patients

What does the study involve?

Participating cardiac centers introduce the safety checklist. The use of the checklist is strongly encouraged but not obligatory. Patients who are operated with the use of the safety checklist are compared with those who are operated without. 30-day and 120-day mortality (death rates), surgical re-exploration, 72-hour stroke and deep sternal wound infections are compared between the groups.

What are the possible benefits and risks of participating?

The benefit of participating is that patient safety may be improved by systematically checking all the possible risk factors for preoperative complications. There is a small risk that the initial operation plan will be adapted. However, these adaptations are meant to increase patient safety and to prevent possible harmful situations.

Where is the study run from?

1. Isala Hospital, Zwolle (Netherlands)
2. Medisch Spectrum Twente (Netherlands)
3. Antonius Hospital Nieuwegein (Netherlands)
4. OLVG (Netherlands)
5. Catharina Hospital (Netherlands)

6. HAGA teaching hospitals (Netherlands)

7. Amphia (Netherlands)

When is the study starting and how long is it expected to run for?

May 2014 to December 2015

Who is funding the study?

Achmea Healthcare (Netherlands)

Who is the main contact?

Mr Alexander Spanjersberg

Contact information

Type(s)

Scientific

Contact name

Mr Alexander Spanjersberg

Contact details

Dr van Heesweg 2

Zwolle

Netherlands

8025AB

Additional identifiers

Protocol serial number

Z528-2

Study information

Scientific Title

Effects of the implementation of a specific cardiac surgery checklist on mortality in 7 Dutch cardiac centers

Study objectives

Implementing a specific cardiac surgery safety checklist in multiple cardiac surgery centers results in lower mortality and major complications.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Committee on Research Ethics of Isala Hospital in Zwolle the Netherlands considered that no further approval was necessary as this is a retrospective study on routine data, 14/08/2014, METC nr 14.08113

Study design

Multicenter observational cohort study during a one-year implementation phase

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Adult cardiac surgery patients

Interventions

Participating centers started to implement the safety checklist from 01/01/2015 and all adult patients undergoing cardiac surgery in one of the participating hospitals were eligible. The use of the checklist was strongly encouraged, but not obligatory. The studied patient population was limited to coronary artery bypass grafting (CABG), surgical aortic valve replacement (AVR), combination of both, and mitral valve surgery (MVS). Patients who were operated on with the use of the safety checklist were compared with those who were operated without.

Intervention Type

Behavioural

Primary outcome(s)

120-day mortality; data retrieved from electronic database of the regional municipal administration

Key secondary outcome(s)

1. 30-day mortality; data retrieved from electronic database of the regional municipal administration
2. 72-hour stroke; data retrieved from active reporting of participating hospital; stroke is defined as a stroke diagnosed by a neurologist (not TIA), within 72 hours after primary surgery.
3. Surgical re-exploration: data from active reporting; surgical re-exploration is defined as every opening of the thorax after primary closure within 30 days after primary surgery. Causes may be bleeding, tamponade or other, but not mediastinitis
4. Deep sternal wound infection (DSWI); data from active reporting; DSWI is defined as deep sternal wound infection within 30 days after primary surgery

Completion date

31/12/2015

Eligibility

Key inclusion criteria

1. Adult cardiac surgery patients
2. Undergoing coronary artery bypass grafting (CABG), surgical aortic valve replacement (AVR), AVR combined with CABG, and mitral valve surgery (MVS)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Data not available on:

1. Type of surgery
2. Use of safety checklist

Date of first enrolment

01/01/2015

Date of final enrolment

31/12/2015

Locations**Countries of recruitment**

Netherlands

Study participating centre**Isala Hospital, Zwolle**

Dr van Heesweg 2

Zwolle

Netherlands

8025AB

Study participating centre**Medisch Spectrum Twente**

Koningsplein 1

Enschede

Netherlands

7512 KZ

Study participating centre**Antonius Hospital Nieuwegein**

Koekoekslaan 1

Nieuwegein

Netherlands

3435 CM

Study participating centre**OLVG**

Oosterpark 9
Amsterdam
Netherlands
1091 AC

Study participating centre**Catharina Hospital**

Michelangelolaan 2
Eindhoven
Netherlands
5623 EJ

Study participating centre**HAGA teaching hospitals**

Els Borst-Eilersplein 275
The Hague
Netherlands
2545 AA

Study participating centre**Amphia**

Molengracht 21
Breda
Netherlands
4818 CK

Sponsor information**Organisation**

Achmea Healthcare

Organisation

Isala Academy

Organisation

Achmea (Netherlands)

ROR

<https://ror.org/00gqmk69>

Funder(s)**Funder type**

Other

Funder Name

Achmea Healthcare

Results and Publications**Individual participant data (IPD) sharing plan**

The dataset will not be directly available, as data ownership is at the participating centers. In the agreement with the participating centers it is stated that data may only be analyzed for the purpose of this study. If there is a request, the participating centers have to be asked for permission to use the data for a new purpose. In the meantime data are held at the national institution: Netherlands Heart Registry.

IPD sharing plan summary

Not expected to be made available