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

Submission date
12/06/2018

Recruitment status
No longer recruiting

Registration date
14/06/2018

Overall study status
Completed

Last Edited
14/06/2018

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
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8025AB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
27/05/2014

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

Age group
Adult

Sex
Both

Target number of participants
The one year study period in 7 Dutch centers will render about 6000 patients undergoing CABG, AVR, AVR+CABG and MVS

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

Sponsor details
Burgemeester Roelenweg 13
Zwolle
Netherlands
8021 EV

Sponsor type
Other

Website
achmea.nl

Organisation
Isala Academy

Sponsor details
Dr Van Heesweg 2
Zwolle
Netherlands
8025 AB

Sponsor type
Hospital/treatment centre

Website
www.isala.nl/academie

Organisation
Achmea (Netherlands)

Sponsor details

Sponsor type
Not defined

Website
https://www.achmea.nl/

ROR
https://ror.org/00gqmky69

Funder(s)

Funder type
Other

Funder Name
Achmea Healthcare

Results and Publications

Publication and dissemination plan
Main article will be submitted summer 2018. Presentation on ESC congress 2018 Munich.

Intention to publish date
01/08/2018

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