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Posterior pericardiotomy for prevention of atrial fibrillation and pericardial effusion after aortic valve replacement

Submission date
25/12/2013

Recruitment status
No longer recruiting

Registration date
08/01/2014

Overall study status
Completed

Last Edited
12/07/2017

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In patients who underwent a heart surgery called coronary artery bypass graft (CABG), posterior pericardiotomy (a surgical procedure carried out on the pericardium of the heart) has been shown to be protective against postoperative atrial fibrillation (abnormal heart rate after heart surgery). This study aims to find out whether it could help patients who underwent valve surgery.

Who can participate?
Patients admitted for aortic valve replacement surgery can participate in this study.

What does the study involve?
Patients are divided randomly into two groups. One group receives posterior pericardiotomy during the valve replacement surgery and the other group, called the control group, receives the standard surgical technique.

What are the possible benefits and risks of participating?
This technique may reduce the occurrence of postoperative atrial fibrillation and accumulation of fluid around the heart in patients who underwent aortic valve replacement surgery.

Where is the study run from?
This study is run from Ochapowski Regional Hospital, Russia.

When is the study starting and how long is it expected to run for?
The study started in October 2013 and is expected to run for 1.5 years.

Who is funding the study?
The study is funded by the Kuban State Medical University, Russia.

Who is the main contact?
Dr Vasily Kaleda
vasily.kaleda@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Vasily Kaleda

Contact details
140, Rossiyskaya str.
Krasnodar
Russian Federation
350086
-
vasily.kaleda@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The efficacy of posterior pericardiotomy in prevention of atrial fibrillation and pericardial effusion after aortic valve replacement

Study objectives
The hypothesis is that posterior pericardiotomy can reduce the incidence of atrial fibrillation and pericardial effusion after aortic valve replacement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kuban State Medical University Ethics Comimttee, 01/10/2013, Protocol #22

Study design
Single-centre non-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Cardiac surgery postoperative atrial fibrillation and pericardial effusion

Interventions
Patients will be randomised to two groups: intervention and control
1. Intervention group: will undergo posterior pericardiotomy in addition to conventional aortic valve replacement
2. Control group: will undergo only conventional aortic valve replacement

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. Mortality
2. The incidence of stroke
3. The incidence of cardiac tamponade

Concerned to in-hospital period.

Secondary outcome measures
1. The incidence of atrial fibrillation, measured with 48-h ECG monitoring and then with daily ECG
2. The incidence of pericardial effusion measured by echo twice after removing chest tubes and before discharge
3. The incidence of left pleural effusion measured by echo twice after removing chest tubes and before discharge
4. Length of stay in hospital

Overall study start date
17/10/2013

Completion date
17/04/2015

Eligibility

Key inclusion criteria
1. Age 18-69 years
2. Informed consent obtained
3. Isolated primary aortic valve replacement

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
69 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Known history of atrial fibrillation before surgery
2. Amiodarone intake before surgery
3. Known history of thyrotoxicosis
4. Pericardial effusion with a maximum pericardial separation of more than 0.5 cm by transthoracic echocardiography (TTE) before surgery
5. Severe chronic obstructive pulmonary disease (COPD)
6. Left ventricular ejection fraction (LVEF) <30%
7. Left atrium (LA) diameter >50 mm
8. Pericardial adhesions
9. Any active inflammatory disease at the time of surgery (including active infection endocarditis)

Date of first enrolment
17/10/2013

Date of final enrolment
17/04/2015

Locations

Countries of recruitment
Russian Federation

Study participating centre

140, Rossiyskaya str.
Krasnodar
Russian Federation
350086

Sponsor information

Organisation
Kuban State Medical University (Russia)

Sponsor details
4, Sedina str.
Krasnodar
Russian Federation
350063
+7 918 377 8155
corpus@ksma.ru

Sponsor type
University/education

Website
http://www.ksma.ru

ROR
https://ror.org/04wa91k02

Funder(s)

Funder type
University/education

Funder Name
Kuban State Medical University (Russia)

Results and Publications

Publication and dissemination plan
Publication in a high-impact peer reviewed journal.

Intention to publish date
01/07/2017

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/02/2017		Yes	No