ISRCTN15411573 https://doi.org/10.1186/ISRCTN15411573

Potential markers to screen benefit after cardiac surgery

Submission date
19/12/2020

Recruitment status
No longer recruiting

Registration date
11/01/2021

Overall study status
Completed

Last Edited
14/01/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Ischemic heart disease is caused by a decrease in blood flow through one or more of the blood vessels that carry oxygen to the heart. It is the leading cause of death worldwide. Despite the current awareness of the disease, there are no good clinical markers to evaluate disease severity and predict a patient's potential benefit after cardiac surgery. This study aims to identify ischemic heart disease specific markers from right atrial appendage tissue (from the right border of the heart).

Who can participate?
Patients undergoing coronary artery bypass grafting (CABG) or aortic valve surgery

What does the study involve?
A biopsy (sample) is taken from the right atrial appendage, and patient records are analysed.

What are the possible benefits and risks of participating?
There are no clinically relevant possible benefits for participants and no significant risks associated with participation in this study.

Where is the study run from?
1. Helsinki University Hospital (Finland)
2. Tampere Heart Hospital (Finland)

When is the study starting and how long is it expected to run for?
December 2012 to July 2020

Who is funding the study?
Finnish government subsidies for medical research block grants and the Finnish Funding Agency for Technology and Innovation (Finland)

Who is the main contact:
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
DNro 286/13/03/02/12

Study information

Scientific Title
Atrial appendage signature RNAs associated with ischemic heart disease severity and surgical outcome

Study objectives
To explore signature RNAs associated with ischemic heart disease severity and surgical outcome after cardiac surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/12/2012, the Operative Ethics Committee of the Hospital District of Helsinki and Uusimaa (Biomedicum 2C, 00029 HUS; +358 (0)471 73021; tuija.sipilainen@hus.fi), ref: DNro 286 /13/03/02/12

Primary study design
Observational

Study design

Multicenter case-control observational study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Ischemic heart disease severity and surgical outcome after cardiac surgery

Interventions
The researchers harvest samples from the right atrial appendage and perform RNA sequencing. After that, they apply bioinformatic analyses and compare RNA-sequenced data to clinical data in order to find ischemic heart disease specific markers from target tissue.

Intervention Type
Other

Primary outcome(s)
Differentially expressed genes in right atrial appendage tissue among patient groups, measured using Trimmomatic, EnsEMBL gene collection v82 and R bioconductor's package edgeR after RNA sequencing after surgery. RNA sequencing data is compared to clinical data from the preoperative period and the 3-month control visit using Pearson R, Mann-Whitney U-test, Student's t-test.

Key secondary outcome(s)
Differentially expressed miRNAs in right atrial appendage tissue among patient groups, measured using Trimmomatic, EnsEMBL gene collection v82 and R bioconductor's package edgeR after RNA sequencing at after surgery. miRNA data is compared to clinical data from the preoperative period and the 3-month control visit using Pearson R, Mann-Whitney U-test, Student's t-test.

Completion date
31/07/2020

Eligibility

Key inclusion criteria
Patients undergoing CABG or aortic valve surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
48

Key exclusion criteria
No surgical intervention

Date of first enrolment
01/01/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Finland

Study participating centre
HUS Heart and Lung Center
Haartmaninkatu 4
Helsinki
Finland
00290

Study participating centre
Tampere Heart Hospital
Elämänaukio 1
Tampere
Finland
33520

Sponsor information

Organisation
Helsinki University Central Hospital

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Government

Funder Name
Finnish government subsidies for medical research block grants

Funder Name
Finnish Funding Agency for Technology and Innovation

Results and Publications

Individual participant data (IPD) sharing plan
Data will be added to the Gene Expression Omnibus (GEO) data repository or another suitable data repository. Data will be available upon request from GEO. The data is anonymized, it cannot be traced back to patient information.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/12/2021	14/01/2022	Yes	No