

Potential markers to screen benefit after cardiac surgery

Submission date 19/12/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/01/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/01/2022	Condition category Circulatory System	<input type="checkbox"/> 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

Study design

Multicenter case-control observational study

Primary study design

Observational

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/02e8hzhf44>

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