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Potential markers to screen benefit after cardiac surgery

Submission date	Recruitment status	[_] Prospectively registered
19/12/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/01/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/01/2022	Circulatory System	

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/12/2012

Completion date
31/07/2020

Eligibility

Key inclusion criteria
Patients undergoing CABG or aortic valve surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
54

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

Sponsor details
Haartmaninkatu 4
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+358 (0)9 471 72432
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Sponsor type
Hospital/treatment centre

Website
http://www.hus.fi/en/Pages/default.aspx

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal, such as Journal of the American College of Cardiology. Statistical analysis will be available as supplementary material after publication.

Intention to publish date

31/12/2020

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