

Investigating the contents of atherosclerotic plaques using novel imaging techniques including PET/MRI

Submission date 04/01/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/01/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/08/2021	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Atherosclerosis is the deadliest disease worldwide. It is caused by the buildup of fats, cholesterol and other substances in and on the artery walls (plaque), which can restrict blood flow. Most deaths are caused by the rupture (bursting) of plaques, leading to arterial thrombosis (blood clot) and occlusion (blockage), resulting in a heart attack or stroke. Early detection of rupture-prone plaques would provide opportunities for treatment before fatal or disabling cardiovascular events. Previous research has shown that factors strongly associated with plaque rupture are inflammation and elevated contents of fat (the lipid core) and blood (hemorrhage within the plaque). Therefore, these plaque characteristics are associated with a high risk of cardiovascular events.

Researchers have developed a new and validated MRI technique for measuring fat and blood within plaques. In this study, for the first time, the aim is to measure not only fat and blood, but also plaque inflammation. The study of correlations between these high-risk plaque features will provide new information on atherosclerotic plaque biology, and will hopefully lead to new methods to identify high-risk individuals.

Who can participate?

Patients aged 80 or under with high-grade carotid stenosis (narrowing of the carotid arteries)

What does the study involve?

All patients undergo one MRI scan and one whole-body PET/MRI scan in order to create images of the carotid arteries.

What are the possible benefits and risks of participating?

The PET scan involves a low dose of radiation, 5 mS. However, the risk to the patients of developing any side effects related to this is considered very low, as their mean age is over 70. The benefit is the possibility that the study contributes to the development of better tests for plaque risk assessment in the future.

Where is the study run from?
Linköping University and Uppsala University (Sweden)

When is the study starting and how long is it expected to run for?
June 2017 to October 2018

Who is funding the study?
1. Henry och Ella Margareta Ståhls Stiftelse (Henry and Ella Margareta Ståhl's Foundation) (Sweden)
2. Swedish Heart-Lung Foundation (Sweden)

Who is the main contact?
Dr Elin Good
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Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 1

Study information

Scientific Title

The DTP FDG-PET-MRI study for assessment of inflammation, lipid-rich necrotic core and intraplaque hemorrhage in the atherosclerotic plaque

Acronym

CARMA-PET

Study objectives

The degree of inflammation in the atherosclerotic plaque is correlated to the quantity of fat (lipid-rich necrotic core) and the quantity of blood (intraplaque haemorrhage), as all these three are associated with plaque rupture.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 12/01/2018, Swedish Ethical Review Authority (Swedish Ethical Review Authority, Box 2110, 750 02 Uppsala; +46 (0)10 475 08 00; registrator@etikprovning.se), ref: 2017/545-31

Study design

Multicenter observational prospective trial

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Atherosclerotic plaque composition in patients with high-grade carotid stenosis

Interventions

In patients with high-grade carotid stenosis the extent of lipid-rich necrotic core and intraplaque hemorrhage is quantified from fat and R2* maps acquired with a previously validated four-point Dixon MRI sequence in a stand-alone MRI. PET/MRI is used to measure 18F-FDG uptake.

Intervention Type

Device

Phase

Not Applicable

Primary outcome measure

1. Lipid-rich necrotic cores (fat) and intraplaque hemorrhage (blood) in atherosclerotic plaques are measured using a novel and thoroughly validated quantitative MRI (qMRI) technique at study baseline
2. Inflammation measured using 18F-fluoro-deoxyglucose (18F- FDG) uptake quantified in the same plaques on images acquired using a simultaneous whole-body PET/MRI scanner at study baseline, as close in time to the qMRI assessment as possible

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/06/2017

Completion date

26/10/2018

Eligibility**Key inclusion criteria**

≥50% carotid stenosis (corresponds to a Doppler flow velocity ≥ 1.3 m/sec at a Doppler angle of 50-60°)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

10-20

Total final enrolment

12

Key exclusion criteria

1. Previous carotid endarterectomy
2. Carotid occlusion
3. Diabetes mellitus
4. Renal failure (GFR <45 ml/min/1.73m²)
5. Inflammatory diseases including malignancies, immunologic disorders
6. Treatment with immunosuppressive/anti-inflammatory agents

Date of first enrolment

01/04/2018

Date of final enrolment

01/10/2018

Locations

Countries of recruitment

Sweden

Study participating centre

Linköping University

Department of Health, Medicine and Caring Sciences

Linköping University Hospital

Linköping

Sweden

58183

Study participating centre

Uppsala University

Department of Surgical Sciences

Section of Radiology & Molecular Imaging

Uppsala University Hospital

Uppsala

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751 85

Sponsor information

Organisation

Henry och Ella Margareta Ståhls Stiftelse (Henry and Ella Margareta Ståhl's Foundation)

Sponsor details

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Sponsor type

Charity

Website

<http://stahl.se/stiftelsen/>

Funder(s)**Funder type**

Charity

Funder Name

Henry och Ella Margareta Ståhls Stiftelse (Henry and Ella Margareta Ståhl's Foundation)

Funder Name

Hjärt-Lungfonden

Alternative Name(s)

Swedish Heart-Lung Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Sweden

Results and Publications

Publication and dissemination plan

1. The study protocol and statistical analysis plan will be available immediately following publication. The documents, however, will not be available in web format, please use the contact details to request copies of the documentation.
2. Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/02/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Elin Good (elin.good@liu.se). Individual participant data that underlie the results reported in published manuscripts will be available immediately following publication, after deidentification (text, tables, figures, and appendices). This information may be shared with investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. The information may be used to achieve aims in the approved proposal. Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in the University's data warehouse but without investigator support other than deposited metadata. Written informed consent from all participants was obtained. All data is anonymized.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/02/2021	No	Yes
Results article	results	09/07/2021	11/08/2021	Yes	No