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

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 04/01/2021 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 05/01/2021 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 11/08/2021 | Circulatory System | |

## 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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Public

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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
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751 85

## Sponsor information

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

**Sponsor details**
c/o Ståhl Invest i Norrköping AB
Garvaregatan 4C
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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 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 |