

Investigation of the use of a radioactive dye in the diagnosis of a build-up of protein deposits within the heart

Submission date 05/09/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/09/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Cardiac amyloidosis is a disease in which proteins accumulate in the heart muscle resulting in loss of its function. In this study, we evaluate a commercially available radioactive imaging compound (Flutemetamol), that has been designed to stick to these accumulated proteins, in the diagnosis of cardiac amyloid disease. Flutemetamol is currently used in the imaging of Alzheimer's disease, to detect protein accumulation in the brain. In this study, we will assess the safety and effectiveness of using Flutemetamol to detect cardiac amyloidosis.

Who can participate?

Participants are recruited from participating study centers in Finland. The requirement for participation is previously diagnosed or excluded cardiac amyloidosis.

What does the study involve?

Participants will undergo imaging of the heart using positron emission tomography (PET) imaging. Radioactive dye (Vizamyl) is administered intravenously to arm vein. Scanning takes 30 minutes. For selected patients, another 15-minute image is acquired after 1-hour. Participants will be given the opportunity to have another imaging scan on a different day, using a different radioactive dye. There are no follow up visits. Patient records are then checked at 1, 3, and 5 years after the imaging to assess any complications arising from the use of the radioactive dye.

What are the possible benefits and risks of participating?

The study might not offer additional health benefits to individual participants. The safety of Flutemetamol is established in previous studies and is routinely used in patient care. Its side effects are rare and generally mild. The physician will inform each participant on possible side effects.

Where is the study run from?

Helsinki University Hospital (Finland)

When is the study starting and how long is it expected to run for?

January 2019 to December 2025

Who is funding the study?

1. Helsinki University Hospital (Finland)
2. Sakari Alhopuro Foundation (Finland)
3. Flutemetamol compound is sponsored by General Electric Healthcare (Finland)

Who is the main contact?

Dr. Valtteri Uusitalo, valtteri.uusitalo@hus.fi

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

70233

Study information

Scientific Title

Clinical validation of quantitative flutemetamol PET/CT in cardiac amyloidosis

Study objectives

The aim of this study is to validate flutemetamol PET for imaging of cardiac amyloidosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 13/02/2020, Helsinki University Hospital district Ethical Committee (HUS ethical committee I, HUS Töölön sairaala, PL 266, 00029 HUS, Finland; +358 (0)403594618; eettiset.toimikunnat@hus.fi), ref: HUS/896/2019

Study design

Longitudinal observational multicenter imaging study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Cardiac amyloidosis including light chain and transthyretin amyloidosis

Interventions

The study aims to validate commercially available positron emission tomography radiotracer Flutemetamol (Vizamyl) to diagnose cardiac amyloidosis. We evaluate the difference in myocardial radiotracer kinetics and signal intensity in patients with no amyloidosis, transthyretin amyloidosis or light chain amyloidosis.

Participants for this study undergo positron emission tomography (PET) imaging. It is similar to computed tomography scanning. Radioactive dye Vizamyl is administered intravenously to arm vein. Scanning takes 30 minutes. For selected patients, another 15-minute image is acquired at 1-hour. PET imaging is painless and doctor discusses possible side-effects of the procedure with each individual before the imaging.

The possibility to participate to further amyloid scintigraphy ("amyloid scan") imaging is offered to those individuals without previous amyloid scintigraphy. Amyloid scintigraphy is a standard procedure similar to PET imaging. It is obtained on a different day using well-established radioactive imaging dye (HMDP).

There are no further follow-up visits after the imaging. Individuals receive a summary of their imaging results by letter and can discuss the results with a principal investigator afterwards if necessary.

To assess the prognostic significance of cardiac Flutemetamol accumulation: follow-up data on diagnoses of heart failure, heart failure hospitalization and total mortality is collected from patient records and Finnish national statistical service (time points 1, 3 and 5 years).

Intervention Type

Other

Primary outcome(s)

Mortality measured using records from the Finnish national statistical service database at 1, 3 and 5 years

Key secondary outcome(s)

1. Heart failure measured using patient records diagnoses at 1, 3 and 5 years
2. Heart failure related hospitalizations measured using patient records at 1, 3 and 5 years

Completion date

31/12/2025

Eligibility

Key inclusion criteria

Previous clinical suspicion of cardiac amyloidosis and currently know the status of their disease (e.g. no amyloidosis, light chain disease, transthyretin)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Pregnancy
2. Age below 18 years
3. Unknown cardiomyopathy

Date of first enrolment

01/08/2019

Date of final enrolment

31/12/2022

Locations

Countries of recruitment

Finland

Study participating centre

Helsinki University Hospital

Meilahti Nuclear Medicine Center

Haartmaninkatu 4

Helsinki

Finland

00290

Study participating centre

Päijät-Häme Nuclear Medicine Center

Päijät-Hämeen keskussairaala

Isotooppilaboratorio

Keskussairaalankatu 7

Lahti

Finland

15850

Sponsor information

Organisation

Helsinki University Central Hospital

ROR

<https://ror.org/02e8hzhf44>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Helsingin ja Uudenmaan Sairaanhoidopiiri

Alternative Name(s)

Helsinki University Central Hospital, HUS

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Finland

Funder Name

Sakari Alhopuro Foundation

Funder Name

GE Healthcare

Alternative Name(s)

Nycomed Amersham

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Sharing of raw data is considered upon reasonable request. Request can be sent to the principal investigator (Dr. Valtteri Uusitalo, valtteri.uusitalo@hus.fi).

Statistical anonymized data can be shared in the case of possible research collaboration when cleared by Helsinki University Hospital ethical board. Study participants consent has not been collected for further data sharing and thus must be cleared by Helsinki University Hospital ethical board and legal counsel case-by-cases basis. Imaging data cannot be routinely shared outside our study due to legal restrictions. Data requests are considered for 3 years after the end of the study.

IPD sharing plan summary

Available on request