ISRCTN45011896 https://doi.org/10.1186/ISRCTN45011896

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	[_] Prospectively registered [_] Protocol
Registration date 02/10/2020	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 29/09/2020	**Condition category** Cancer	[_] Individual participant data [_] 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 administrated 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. It's 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
Dr Valtteri Uusitalo

ORCID ID
https://orcid.org/0000-0001-7345-7122

Contact details
Vaskiniementie 1, A11
Helsinki
Finland
00200
+358 (0)405358011
vauusi@utu.fi

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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

Secondary outcome measures
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

Overall study start date
01/01/2019

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

Age group
Adult

Sex
Both

Target number of participants
50

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

Sponsor details
Haartmaninkatu 4 Rakennus 1
Helsinki
Finland
00290
+358 (0)504271445
antti.loimaala@hus.fi

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsingin ja Uudenmaan Sairaanhoitopiiri

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

Publication and dissemination plan

Planned publication in high-impact peer-reviewed cardiology journal.

Intention to publish date
31/12/2023

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