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Exploring new MRI techniques - a study in healthy volunteers and healthy patients

Submission date
09/11/2023

Recruitment status
Recruiting

Registration date
14/11/2023

Overall study status
Ongoing

Last Edited
22/07/2024

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-different-ways-of-doing-mri-scans-hevomri

Background and study aims
Magnetic Resonance Imaging (or MRI) plays an important role in detecting, diagnosing, and monitoring different diseases in the body. We often use contrast-enhanced MRI, which enhances and improves the quality of the MRI images. This type of MRI involves an injection of a chemical substance often called gadolinium-based contrast agent.
In this study we aim to develop novel imaging methods for cancer diagnostics and treatment monitoring. When developing a new method, we need healthy volunteers to help define the limits of "normal." Similarly, it is useful to know what the images look like in healthy patients, i.e. patient with a known genetic predisposition to cancer but without manifested cancer. Healthy volunteers and healthy patients are given the same procedure that the patient group receives. Investigators learn about the disease process by comparing the healthy volunteers' and healthy patients' images to the cancer patients' images.

Who can participate?
Magnetic Resonance Imaging (MRI) is an important tool used by doctors to detect, diagnose, and keep an eye on various diseases inside the body. We often use a special type of MRI that uses a substance known as a "contrast agent" to make the pictures even clearer and more helpful. You can either receive this substance through an injection into your body or take it as a drink before the scan.
In this research project, we are working on creating new ways to take pictures of cancer and keep track of how it is doing during treatment. To do this, we need the help of some people who are in good health to make sure we understand what a normal picture looks like. We also want to know what the pictures look like in people who are healthy but might have a higher chance of getting cancer because of their genes. These healthy volunteers and patients get the same imaging procedure that people with cancer get. By comparing the pictures from the healthy volunteers and patients to those from people with cancer, we can learn more about how the disease works.

What does the study involve?
We would like you to come for up to three study visits where you will have an MRI scan. We are studying three different ways of taking pictures: one involves getting an injection of a safe substance and then having a scan; another involves drinking a sweet drink and then having a scan; and the last one just requires an MRI scan. You might be asked to take part in one, two, or all three of these scans, depending on your agreement and if you are eligible. If you agree to have more than one scan, we will try to do them on the same visit. You can choose to take part in one scan and not in the others. If you are willing to have more than one scan, it will help us compare the different ways of taking pictures to see what each one is good for.
If possible, we would also like to check how reliable each method is by asking some people to come for an extra imaging session at some point during the study. This is optional and will help us understand the methods better.
During your visit(s), we might ask you to give a small sample of your blood. We will use this to check the levels of some simple substances in your blood. It will help us understand the pictures better. You do not have to do this if you do not want to.

What are the possible benefits and risks of participating?
Taking part in this study may not directly help you, but it could help doctors find better ways to check for and keep track of illnesses without using invasive methods. You will not be paid for taking part, we can cover your travel and parking costs.
Potential risks
MRI Scans: MRI scans are safe and do not involve X-rays or radioactivity. Some people might feel a bit closed-in (claustrophobic) or bothered by the noise, but you will be given earplugs and a squeeze-ball to help you feel more comfortable. The imaging software and hardware used are for research and not yet approved for routine diagnosis.
Incidental Findings: Although the scans are not part of your medical record, if we notice anything unusual, we will consult a specialist who may need to discuss it with you and your doctor.
Cannulation (inserting a small tube into a vein): This is a common procedure and is generally safe, but it might cause some discomfort or bruising at the insertion site. The cannula will be removed immediately after the scan.
Injection containing a substance called pyruvate: The injection is generally safe, with only mild and short-lasting side effects like flushing, feeling hot, dizziness or a metallic taste. Allergic reactions are highly unlikely, but we are prepared to manage any issues that may arise.
Sweet drink containing a substance called deuterated glucose: Glucose is a natural sugar that our body uses for energy, and deuterium is a safe form of hydrogen that is also found naturally in small amounts in our body. Scientists have previously studied water and glucose containing deuterium in people, and they did not find safety concerns. Any potential side effects will be managed by our team.

Where is the study run from?
The study takes place in Cambridge University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2022 to December 2025

Who is funding the study?
Cancer Research UK

Who is the main contact?
cuh.radiologyresearch@nhs.net

Contact information

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Principal Investigator

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
319308

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HeVoMRI v2.1 17 June 2023, IRAS 319308

Study information

Scientific Title
Development of novel multinuclear magnetic resonance techniques in healthy volunteers and healthy patients

Acronym
HeVoMRI

Study objectives
Significant differences exist in the imaging characteristics observed using Hyperpolarised MRI, sodium MRI and DMI between healthy volunteers and healthy patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/06/2023, Yorkshire & The Humber - Leeds East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8018; leedseast.rec@hra.nhs.uk), ref: 23/YH/0127

Study design
Non-randomized physiological imaging study

Primary study design
Observational

Secondary study design
Non-randomized physiological study

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Healthy volunteers and healthy patients with known specific genotypes

Interventions
This is a non-randomised, physiological imaging study split into three imaging techniques across the body including: brain, chest, abdomen/pelvis, breast or extremities.

MR imaging:
1. Following injection of 13C-pyruvate, using dynamic 13C MRI and MRSI in up to 40 healthy volunteers/healthy patients
2. Using Sodium MRI and MRSI in up to 40 healthy volunteers/healthy patients
3. Following oral consumption of a deuterated glucose drink or deuterated water, using dynamic deuterium metabolic MRI and MRSI imaging (DMI) in up to 40 healthy volunteers/healthy patients

Healthy volunteers/healthy patients will be allocated to one of these imaging techniques by the Chief Investigator or delegate. This will be based on the availability of kits for the Hyperpolarised MRI study, the availability of the deuterated drink for the DMI study and/or the availability of the research MRI scanner. If healthy volunteers/healthy patients are willing, they may be recruited to all three arms to enable direct comparison.

Each participant will be offered an optional repeat scan within 14 days of their first scan. This will either be a duplication of their first scan in order to determine whether these imaging techniques are repeatable or will be one of the other imaging techniques to determine whether these imaging techniques can provide complementary data when used in combination. Refusal to take part in this optional imaging will not impact their participation in the rest of the study.

Participants will not receive more than two injections of 13C-pyruvate and will not receive more than two deuterated glucose or two deuterated water drinks.

This single-centre study is being conducted at Addenbrooke’s Hospital, Cambridge Biomedical Campus, UK.

Intervention Type
Other

Primary outcome measure
Using MRI imaging:
1. 13C. Spatial maps of area under the curve (AUC) timecourse sums of signals from hyperpolarized pyruvate, lactate, and any other metabolites detected, and ratios between these metabolite AUCs. Also estimates of the kinetic rate constants of conversion between injected tracer pyruvate and the metabolites formed (lactate, other). The timecourse typically covers approximately 1 minute beginning approximately 16 seconds after the start of injection.
2. DMI. Spectral peak intensity ratios between deuterated water, glucose, glutamate (brain only), lactate and lipids. These will be either in spatial maps derived from 3D spectroscopic imaging, or in unlocalized spectra from the whole sensitive volume of the coil.
3. Sodium. Maps of estimated millimolar sodium content over the 3D volume of tissue

investigated. Optionally also maps of the ratio of intracellular-weighted signal to total sodium signal.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/08/2022

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Inclusion criteria for healthy volunteers:
1. Over 18 years old
2. Able to and provide written informed consent to participate
3. If female, postmenopausal or if women of childbearing potential (WOCBP) using a suitable form of contraception
4. Capable of undergoing a minimum of one study visit

Inclusion criteria for healthy patients at risk for hereditary metabolic disease:
1. Over 18 years old
2. Able to and provide written informed consent to participate
3. If female, postmenopausal or if of childbearing potential (WOCBP) using a suitable form of contraception
4. Capable of undergoing a minimum of one study visit
5. Carrying a pathogenic variant in the genes for succinate dehydrogenase and undergoing asymptomatic surveillance but without tumour manifestation

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
The presence of any of the following will preclude participation as determined by the delegated investigator:
1. Contraindication or inability to tolerate MRI

2. Pregnant or actively breastfeeding woman
3. If using an intrauterine contraceptive device (IUCD) as a method of contraception the device should be MRI-safe at 3 T (researcher to confirm)
4. Clinically significant cardiac, pulmonary or neurological diseases as determined by the investigators
5. Laboratory abnormalities that may impact the study results although no screening will be required for entry into the study.
6. Any other significant medical or psychiatric history rendering the subject ineligible as deemed by the investigators

Date of first enrolment
29/08/2023

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
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Sponsor information

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Cambridge University Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.cuh.nhs.uk

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Research organisation

Funder Name
Cancer Research UK Cambridge Institute, University of Cambridge

Alternative Name(s)
Cancer Research UK Cambridge Institute, CRUK Cambridge Institute, CRUK CI, CRUK-CI

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Audiences for this research:
1. Scientific community
2. Funders, sponsors including NHS, ethics committees
3. Patients and the public

Dissemination activities will include:
1. Abstracts, posters and talks for national and international scientific conferences
2. PPI events
3. Use of electronic media such as websites and specialised social networks such as Linkedin and

ResearchGate
4. Publications including Full, Executive Summary and Plain English Summary reports of the research, peer review journals and local NHS/University of Cambridge newsletters. Whenever possible, open access to publications will be sought.

This study may form part of a PhD thesis for a PhD student working in the research team.

Intention to publish date
01/10/2026

Individual participant data (IPD) sharing plan
Data requests can be submitted starting 9 months after article publication and the data will be made accessible for up to 24 months. Extensions will be considered on a case-by-case basis. Access to trial IPD can be requested by qualified researchers engaging in independent scientific research and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA). For more information or to submit a request, please contact cuh.radiologyresearch@nhs.net.

IPD sharing plan summary
Available on request