ISRCTN62305334 https://doi.org/10.1186/ISRCTN62305334

STARBEAM-X: Assessing blood flow in brain tumors using MRI before and after targeted radiation treatment

Submission date
10/02/2023

Recruitment status
No longer recruiting

Registration date
27/02/2023

Overall study status
Ongoing

Last Edited
27/02/2023

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
The purpose of this study is to use an additional type of picture on the MRI scanner to look into the way brain tumours (cancer that has spread to a part of the brain) behave. In particular, we are interested in using this picture to help us work out which patients develop radiotherapy damage after their treatment.
We are very much hoping that the understanding that we develop in this study will lead to a larger study in future to improve the information MRI scans can yield in secondary brain tumours.

Who can participate?
Patients with brain metastases (secondary tumour in the brain) from a primary cancer in another part of the body who have not had previous radiotherapy to the brain or previous surgery to remove the metastasis can participate.

What does the study involve?
If you agree to take part, we will ask you to either sign a consent form or give verbal telephone consent. During the verbal consent process, we will fully explain the study to you including the possible risks of participation and as much time as you require to discuss any concerns or questions you have. This will be fully recorded in your medical notes and will be followed up with written consent whenever possible. When you attend for your radiotherapy planning MRI scan, our radiographers will know to take an extra picture whilst you're having your scan. This will mean an additional 5 minutes lying down in the MRI scanner.
If you consent to take part in the study, we will also collect some information in relation to your previous cancer treatment from your hospital records. All of the information that is collected will be kept anonymous and securely stored by the research team working within this study.
Once you have undergone your MRI scan and completed radiotherapy, you will continue to have regular MRI scans under the care of your oncology team. For a two year period after your treatment, we will record the results of any further MRI scans that you have to assess how you have responded to radiotherapy. We may use your original MRI scans to help us in making decisions about what your future scans might show, particularly if there is a concern that you may have developed radiotherapy damage.

What are the possible benefits and risks of participating?
By taking part, you will be helping us to gather more information about how tumours in the brain respond to radiotherapy and who is at risk of developing radiotherapy damage. This could help guide our radiotherapy treatments in the future and improve patient care.
MRI scanners don't use radiation, so you will not experience any radiation exposure from extra time in the scanner. Some people do find MRI scanning difficult to undergo because of difficulty in small, enclosed spaces and additional time lying in the scanner could cause some people distress.

Where is the study run from?
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2021 to December 2025

Who is funding the study?
1. Siemens Healthcare Ltd (UK)
2. Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Who is the main contact?
Dr Joanne Lewis
Joanne.lewis@nhs.net

Contact information

Type(s)
Principal Investigator

Contact name
Dr Joanne Lewis

Contact details
Freeman Hospital
Freeman Road
Newcastle upon Tyne
United Kingdom
NE7 7DN
+44 191 21 38471
Joanne.lewis@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
304723

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52164, IRAS 304723

Study information

Scientific Title
Dynamic susceptibility contrast MRI Perfusion assessment of brain metastases: baseline characteristics and the study of pattern of perfusion change in suspected radionecrosis post-stereotactic radiosurgery (STARBEAM-X)

Acronym
STARBEAM-X

Study objectives
Baseline MRI perfusion is clinically useful in assessing perfusion status of different types of brain metastases and in helping to diagnose radionecrosis on future post-treatment MR imaging

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/03/2022, Leicester Central Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 207 104 8199; leicestercentral.rec@hra.nhs.uk), ref: 22/EM/0057

Study design
Interventional non randomized

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Brain cancer

Interventions
When the patient attends for their radiotherapy planning MRI scan, they will undergo the conventional imaging sequences as per the standard of care and, during this scan, they will also

undergo additional MRI perfusion sequences. This will entail them lying still on the scanner for a further five minutes. No additional doses of contrast or any other agent will be required to facilitate these scan sequences. On completion of this scan, research participants will not undergo any additional interventions as part of this study.
MR perfusion sequence data will be interrogated by a consultant neuroradiologist. This data will be recorded by the study investigators and analysed using appropriate statistical methods. Research participants' progress will be monitored for a 24-month period. As the current standard of care dictates, these patients will undergo 3-monthly MRI scanning. Results of follow-up MRI scans will be recorded. If any research participants develop symptoms or radiological signs of possible radionecrosis (radiation damage) - their baseline imaging they underwent as part of the study will be assessed in comparison to their current imaging with the hope that this will aid in the diagnostic process.

Intervention Type
Other

Primary outcome measure
1. Baseline perfusion characteristics of host cerebral vascular environment (measured in rCBV on MRI)
2. Baseline perfusion characteristics of brain metastases from a selection of primary sites (measured in rCBV on MRI)

Secondary outcome measures
1. Correlation between baseline perfusion characteristics of brain metastases and primary site of malignancy (descriptive stats – correlation coefficient)
2. Inter-tumour variability in baseline perfusion characteristics in patients with more than one brain metastasis (descriptive stats)

Exploratory:
3. To identify patients with suspected radionecrosis during data collection phase 1 and analyse baseline perfusion characteristics with a view to identifying possible risk associations – measured in follow-up period up to 2 years (descriptive)

Overall study start date
11/10/2021

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Age of 18 years or above on the day of recruitment
2. Have one or more brain metastases from an extracranial primary solid malignancy
3. Accepted for stereotactic radiosurgery to one or more brain metastases following discussion at the local SRS MDT
4. Must have never received any form of prior radiotherapy to the brain

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. Age < 18 years old at the time of eligibility screening
2. Patient has received prior radiotherapy to the brain

Date of first enrolment
09/05/2022

Date of final enrolment
09/11/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Freeman Hospital
Newcastle Upon Tyne Hospital Trust
Freeman Road
High Heaton
Newcastle
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details

1st Floor Regent Point
Regent Farm Road
Gosforth
Newcastle-upon-Tyne
England
United Kingdom
NE7 7DN
-
aaron.jackson@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
Siemens

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Funder Name
Newcastle upon Tyne Hospitals NHS Foundation Trust

Alternative Name(s)
Newcastle upon Tyne Hospitals NHS Trust

Funding Body Type

Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/01/2026

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.2	24/03/2022	24/02/2023	No	Yes
HRA research summary			28/06/2023	No	No