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Advanced hyperspectral imaging during brain tumour surgery

Submission date
04/04/2022

Recruitment status
No longer recruiting

Registration date
01/06/2022

Overall study status
Completed

Last Edited
17/06/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Brain surgery operations include brain tumour resection and procedures relating to blood vessel abnormalities. Each year in the UK, about 70,500 patients are diagnosed with a brain tumour, 5,000 of whom undergo surgery. About 1,000 patients undergo blood vessel surgery. There is an acute need to improve outcomes for affected brain tumour patients. Patients undergoing surgery have significantly improved outcomes and increased life expectancy if complete tumour removal is achieved. However, close to 30% of patients are left with residual tumour tissue after surgery. Successful surgery indeed mandates maximal safe tumour removal: surgeons need to avoid damaging sensitive areas that undertake vital functions and preserve crucial nerves and blood vessels. Even with the most advanced current techniques, it is not possible to always reliably identify the tumour and critical structures during surgery. Furthermore, because one cannot objectively measure the blood supply and oxygenation of brain tissue during surgery, it is difficult to judge if the injury is being caused during the operation. The aim of this study is to obtain images during brain surgery using a new type of surgical non-contact camera system. The study will obtain video images at the various stages of the operation. This will not alter the operation performed. The data obtained will also be used to develop the system's key computer-processing features. This will enable real-time information to be given to the surgeon whilst they are performing the procedure and has the potential to make neurosurgery safer and more precise.

Who can participate?
Patients aged 18 years and over who are scheduled for elective surgery for a diagnosis of a brain tumour, an arteriovenous malformation, or an intracranial aneurysm

What does the study involve?
The study involves taking additional video images during neuro-oncology and neurovascular operations which will extend the operation by up to 15 minutes. The operation will be completed in the usual manner and the surgeon will not use any of the acquired intraoperative data to guide surgical management.

What are the possible benefits and risks of participating?
There will be no immediate direct benefits to those taking part, but the information acquired from this study will help improve the future treatment of people undergoing brain surgery.

Where is the study run from?
King's College NHS Foundation Trust (UK)

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

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Mr Jonathan Shapey
Jonathan.shapey@kcl.ac.uk

Study website
https://www.neurohsi.uk

Contact information

Type(s)
Principal Investigator

Contact name
Mr Jonathan Shapey

Contact details
9th Floor
Becket House
1 Lambeth Palace Road
London
United Kingdom
SE1 7EU
+44 (0)20 7836 5454
Jonathan.shapey@kcl.ac.uk

Type(s)
Scientific

Contact name
Mr Jonathan Shapey

Contact details
9th Floor
Becket House
1 Lambeth Palace Road
London
United Kingdom
SE1 7EU

+44 (0)20 7836 5454
Jonathan.shapey@kcl.ac.uk

Type(s)
Public

Contact name
Miss Sabina Patel

Contact details
Denmark Hill
London
United Kingdom
SE5 9RS
+44 (0)203 299 9000
coordinator@neurohsi.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
284230

ClinicalTrials.gov number
NCT05294185

Secondary identifying numbers
IRAS 284230, CPMS 51752

Study information

Scientific Title
A prospective observational study to evaluate the use of an intraoperative hyperspectral imaging system in neurosurgery

Acronym
NeuroHSI

Study objectives
To correlate hyperspectral imaging data with analysis of the corresponding biopsied brain tumour tissue and to correlate intraoperative blood supply and oxygenation levels generated from the hyperspectral imaging (HSI) data with the surgical timeline in patients undergoing blood vessel surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 23/02/2022, London - Westminster Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8066; abitha.paimpillichalil@hra.nhs.uk), ref: 22/LO/0046

Study design
Single-centre cohort observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Neurosurgery

Interventions
In this project, the researchers will use a HSI imaging system to record data in 81 patients undergoing brain including 63 patients with brain tumours and 18 patients suffering from brain vessel abnormalities. Using this data they will develop key computer-processing features to enable real-time image interpretation.

Intervention Type
Other

Primary outcome measure
Intraoperative oxygenation evaluated using hyperspectral imaging data at 5-10 data points within a 15-minute intraoperative period

Secondary outcome measures
1. Imaging data relevant to the primary pathology acquired at 3 months
2. Any adverse events regarding the safety of the study will be recorded in the first 3 months

Overall study start date
15/09/2021

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Adult patients aged 18 years and over
2. Patients with a diagnosis of a brain tumour (any type), arteriovenous malformation (AVM) or aneurysm who are scheduled for elective surgery
3. Patients able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
81

Total final enrolment
84

Key exclusion criteria
1. Patients under 18 years of age
2. Patients who have previously had brain surgery

Date of first enrolment
01/04/2022

Date of final enrolment
16/06/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College London

Sponsor details
Room 5.31
James Clerk Maxwell Building
57 Waterloo Road
London
England
United Kingdom
SE1 8WA
+44 (0)2078483224
reza.razavi@kcl.ac.uk

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan
Results from this study will be used as part of an educational project (e.g. PhD).

Results from this research study will be made publicly available through the study website (https://www.neurohsi.uk) and through the publication of open-access research papers, presentation of results at scientific meetings, patient events, and online via King's College London and relevant charity websites/social media.

All identifiable personal data used for research will be anonymised before the publication of the results.

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made 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?
HRA research summary			28/06/2023	No	No