ISRCTN95629670 https://doi.org/10.1186/ISRCTN95629670

Using technology called intraoperative monitoring (IOM) to monitor your brain during surgery

Submission date 31/08/2023	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 06/09/2023	**Overall study status** Ongoing	
Last Edited 25/11/2024	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Neurosurgery for brain tumors has two main goals: removing as much of the tumor as possible to increase survival and preventing problems after surgery to enhance quality of life. Currently, there isn't strong evidence from research studies that clearly shows whether using a technique called intraoperative neuromonitoring (IOM) is beneficial. We want to investigate if using IOM during surgery leads to better results for patients. We'll be looking at whether it helps protect their ability to move and also how much of the tumor can be taken out.

Who can participate?
People over the age of 18 years old who have a contrast-enhancing motor eloquent tumour. A "contrast-enhancing motor eloquent tumor" refers to a type of brain tumor that shows up really well in special pictures of the brain, thanks to a dye used during the scan. This dye makes the tumor stand out. The term "motor eloquent" means the tumor is in a spot of the brain that's responsible for controlling important body movements. So, if there's a tumor there, it could affect a person's ability to move properly. "Eloquent" in this case means this part of the brain does crucial things, like helping us move.

What does the study involve?
Surgery is performed with or without IOM and patients undergo clinical neurological examinations, before and after surgery (24 hours) and at follow-up (1 month)

What are the possible benefits and risks of participating?
As this is an observational study there are no extra risks or benefits in participating

Where is the study run from?
Odense University Hospital (Denmark)

When is the study starting and how long is it expected to run for?
May 2021 to March 2027

Who is funding the study?
Odense University Hospital (Denmark)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
21/64369

Study information

Scientific Title
Intraoperative monitoring (IOM) versus no IOM during surgical resection of contrast enhancing motor eloquent tumors- two comparable prospective observational cohorts

Study objectives
To examine whether the use of IOM vs no IOM has an impact on the extent of resection (EOR) of contrast enhancing lesion (absolute and relative volume) on early postoperative MRI (24-72h) and to see if there is a difference in patientes' motor function after surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/12/2021, Region Syddanmark (Damhaven 12, Vejle, 7100, Spain; +45 65412504; magnus.pedersen@rsyd.dk), ref: 21/64369

Primary study design
Observational

Study design
Single-centre prospective observational cohort study

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Evaluation of motor function in patients having surgery with or without intraoperative monitoring for motor eloquent braintumours.

Interventions
Patients will undergo a clinical neurological examination prior to surgery which will include MCRS, NIHSS, six-spot-step test, 9-hole peg test, hand dynamometer, 10 timed walk test. Their surgery will then be performed with ot without intraoperativ monitoring (IOM) based on availability of IOM. If IOM is used, subcortical mapping with a monopolar stimulation suction will be used to guide the surgeons with regards to proximity of corticospinal tracts and the lowest subcortical mapping threshold will be registered.
24 hours post op the patients will undergo the same clinical evaluation as described above. Patients will also recieve an MRI scan to evaloate extent of tumour resection. At one month follow-up the patients will again undergo the same neurological examination where Seizure history (change in Engel classification or antiepileptic drugs (AED)), change in Karnofsky performance scale and patients' global impression of change will also be avaluated.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Extent of resection (EOR) of contrast enhancing lesion (absolute and relative volume) on early postoperative MRI (24-48h)
2. Change in motor function (measured in MCRS, NIHSS, six-spot-step test, 9-hole peg test, hand dynamometer, 10 timed walk test, patients' global impression of change), 24 hours post op and 1 month post op.

Key secondary outcome(s)
1. Seizure history (change in Engel classification or antiepileptic drugs (AED)) after 1 month
2. Functional impairment measured using the Karnofsky performance scale at baseline and 1 month
3. Completeness of resection of fluorescein under the microscope judged by the surgeon at time of surgery
4. Surgeons impression on usefulness of intraoperative guidance at time of surgery

Completion date
31/03/2027

Eligibility

Key inclusion criteria

1. Over the age of 18 years
2. Indication for resection of contrast enhancing lesion in MRI (HGG/GBM, MET)
3. Intention to reach either GTR or CRET
4. Motor eloquence defined as closer than 20mm to either the CST (measured in preoperative DTI) or to the precentral gyrus

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Vulnerable persons such as pregnant woman or children
2. Emergency cases
3. Tumors involving both hemispheres

Date of first enrolment
15/09/2023

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Denmark

Study participating centre
Odense University Hospital
J.B. Winsløws vej 4
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Denmark
5000

Sponsor information

Organisation
Odense University Hospital

ROR
https://ror.org/00ey0ed83

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Odense Universitetshospital

Alternative Name(s)
Svendborg Sygehus, Odense University Hospital, OUH

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Denmark

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be stored in a non-publicly available repository (REDCap - Open Patient data Explorative Network, https://www.open.rsyd.dk).
Qualified researchers can request access to study data and a complete deidentified dataset will be made accessible, together with a data dictionary. Requests for access to the data can be made by sending an email together with a research plan to mads.groenhoej@rsyd.dk.
Additional related documents will also be available upon request (eg. study protocol, statistical analysis plan, informed consent form).

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/09/2023	No	Yes
Protocol file	version 1	01/11/2021	04/09/2023	No	No