

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

Submission date 31/08/2023	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/09/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/11/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design

Single-centre prospective observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment, Safety, Efficacy

Participant information sheet

See study outputs table

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 or without intraoperative 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 receive an MRI scan to evaluate 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 evaluated.

Intervention Type

Procedure/Surgery

Primary outcome measure

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.

Secondary outcome measures

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

Overall study start date

01/05/2021

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50-100

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

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5000

Sponsor information

Organisation

Odense University Hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.ouh.dk/wm259883>

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

Publication and dissemination plan

A final trial report will be written for publication in an international peer review journal, and trial results will be presented at international meetings.

Intention to publish date

31/03/2028

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