Outcomes of neuro-oncology and skull base patients during COVID-19 pandemic: national cohort study (CovidNeuroOnc)

There is an urgent need to understand the impact of the COVID-19 pandemic on decision making and outcomes in neuro-oncology and skull base patients. Several organisations, professional societies and charities have issue guidelines [1-5]. Capturing real-world data and sharing national experience will inform the management of this complex group of patients with brain tumours throughout the COVID-19 pandemic.

In order to contribute to CovidNeuroOnc you must first secure research/audit approval, according to local regulations. This short protocol has been written to support that process. We encourage all stakeholders (local investigators, ethics committees, audit committees, institutional review boards) to work as quickly as possible to approve this project. **This investigator-led, non-commercial, non-interventional study is low risk.**

Study objectives

Primary objective

- To determine whether the COVID-19 pandemic changed the management decision in patients with newly-diagnosed or recurrent brain tumours

Secondary objectives:

- Determine the use of best supportive care
- Determine the use of oncology treatment in glioma without histology diagnosis
- Determine the use of surgery at initial diagnosis or recurrence
- Determine the use of radiotherapy at initial diagnosis or recurrence
- Determine the use of radiosurgery for brain metastasis at initial diagnosis or recurrence
- Determine the use of chemotherapy at initial diagnosis or recurrence
- Determine the overall survival of treated high-grade glioma
- Determine the overall survival of untreated high-grade glioma

Eligibility criteria:

Inclusion:

- Newly-diagnosed brain tumour based on CT/MRI that radiologically is low- or high-grade glioma, primary CNS lymphoma, meningioma, vestibular schwannoma, metastases, or other tumour not including pituitary tumours
- Age ≥ 16 years
- Patients discussed at weekly neuro-oncology MDT meeting

Exclusion

- Paediatric patients aged 0-15 years
- Pituitary tumours

Study period

- The study will be open from 1 April 2020 until 30 June 2020 (3 months). All participating sites should collect data throughout this period.

Patient enrolment

Patients should be identified prospectively at the weekly neuro-oncology MDT as either:

- Newly-diagnosed brain tumour
- Recurrent brain tumour

Patient management should be tracked along the clinical pathway to ensure complete data capture is possible

Outcomes

Primary outcome:

- Proportion of patients with a change in brain tumour management

Secondary objectives:

- Proportion managed with best supportive care
- Proportion with CT/MRI appearance of glioma who undergo oncology treatment without histology confirmation of the tumour
- Proportion undergoing surgery at initial diagnosis or recurrence
- Proportion undergoing radiotherapy (dose and fractionation) at initial diagnosis or recurrence
- Proportion undergoing radiosurgery for brain metastases initial diagnosis or recurrence

- Proportion undergoing chemotherapy (type, dose and cycles) at initial diagnosis or recurrence
- Time to death in treated high-grade glioma
- Time to death in untreated high-grade glioma

Data collection

The study protocol will be approved by the audit and clinical governance committee of each participating hospital where required and registered locally as a service evaluation. Data will be collected on paper forms or directly online, with all records subsequently entered electronically into Castor EDC (Castor EDC, Amsterdam, Netherlands). Castor EDC is a validated system approved by external auditors and complies with all applicable laws and regulations, including ICH E6 Good Clinical Practice (GCP), 21 CFR Part 11, EU Annex 11, General Data Protection Regulation (GDPR), HIPAA (US), ISO 9001 and ISO 27001.

Only anonymised data will be uploaded to the database. **No patient identifiable data will be collected.** Data collected will be on:

- Participating site
- Age category
- Sex (M / F)
- ECOG/WHO performance status
- Newly-diagnose
- Date of CT/MRI and radiological diagnosis
    - Low-grade glioma
    - High-grade glioma
    - Glioblastoma
    - Primary CNS lymphoma
    - Meningioma
    - Vestibular schwannoma
    - Metastases (and number)
    - Other
- Date of MDT
- Date of surgery and type (biopsy / resection)
- Radiotherapy given (dose and fractionation) and start date
- Radiosurgery given (dose) and date
- Chemotherapy given (type, dose and cycles) and start date
- Data of death (high grade glioma only)
- COVID+ infection rate during treatment pathway

The study will be carried out in accordance with national guidelines, as well as the basic principles of the protection of the rights and dignity of Human Beings, as set out

in the Helsinki Declaration (64th Assembly Fortaleza, Brazil, in October 2013), and according to current legislation.

Local approvals

The principal investigator at each participating site is responsible for obtaining necessary local approvals in line with their hospital's regulations. Collaborators will be required to confirm that a local approval is in place at the time of uploading each patient record to the study database.

Principal investigators should discuss with the relevant personnel whether it is possible to expedite the approvals process in view of the urgency of global pandemic. Whatever approvals pathway is followed, it should be highlighted that this is an investigator-led, non-commercial, observational study which is extremely low risk, as only routinely available non-identifiable data will be collected.

Statistical analysis

A detailed statistical analysis plan will be written. Analyses will be overseen by the study investigators. Reports will include description of the primary and secondary outcomes in the cohort.

Authorship

Collaborators from each site who contribute patients will be recognised on any resulting publications as PubMed-citable co-authors. A corporate authorship model will be used (example: https://pubmed.ncbi.nlm.nih.gov/29452941).

References

1. https://www.nice.org.uk/guidance/ng161
2. https://www.nice.org.uk/guidance/NG162
3. https://www.rcr.ac.uk/sites/default/files/neuro-oncology-treatment-covid-19.pdf
4. https://www.bnos.org.uk/wp-content/uploads/2020/03/Adult-neuro-oncology-service-provision-during-COVID-outbreak_SBNS-BNOS.pdf
5. https://www.bnos.org.uk/wp-content/uploads/2020/03/TBTC-advice-adult-brain-tumours-during-COVID-outbreak-BNOS_final_27.3.20.pdf