Safety and feasibility of the use of cryoablation in patients with brain neoplasm

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Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON53649

Source
ToetsingOnline

Brief title
Cryoablation of brain neoplasm

Condition

- Miscellaneous and site unspecified neoplasms benign
- Head and neck therapeutic procedures

Synonym
brain neoplasm, brain tumors

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W, Boston

Scientific,Boston Scientific Cooperation International

Intervention

Keyword: brain neoplasm, Cryoablation, neurosurgery

Outcome measures

Primary outcome

The primary outcome is to assess the safety and feasibility of cryoablation in patients with brain neoplasm. Safety will be expressed in terms of severity and frequency of the following complications: postoperative intracranial bleeding, wound infection, epilepsy, brain edema, neurological deficit, and aphasia. The feasibility will be expressed in terms of operation time (in minutes), blood loss during the intervention (in milliliters), and practicability. Technical failures during intervention will also be investigated.

Secondary outcome

The secondary parameter:

• The conformation of dead tumor cells by pathologist which have been cryoablated during surgery

• The confirmation of reaching macroscopic tumor edges using intraoperative ultrasound (YES/NO). Pictures in 2 directions of the ultrasound will be made to objectify

• The progression free survival during the entire study period (3 months)

• Overall survival during the entire study period (3 months)

• Progression free survival and overall survival of the different tumors will be compared to matched historic controls

• Safety and feasibility will be compared to historic matched controls

Study description

Background summary

There are only limited surgical treatment options like microneurosurgery or biopsy for brain tumors . However, very recently several cases have been presentedin the literature using a cryoablation technique. Cryoablation offers precise and safe lesion targeting with minimal blood loss, is minimally invasive and the ice-cone formation within the tumor can be monitored by several imaging techniques. Cryoablation could also potentially be used for non-resectable tumors. Furthermore, cryoablation could have a potential immunological effect in some malignant brain tumors and have been shown to open blood brain barrier which could be very interesting for drug targeting. Cryoablation could thus be of high value in the minimal invasive treatment of several brain tumors.

Study objective

This study is performed to investigate the safety and feasibility of cryoablation during operation in adults in several brain tumors like gliomas, meningiomas, and brain metastasis. The primary objective is to assess safety in terms of complications rate & morbidity and feasibility, such as operation time, blood loss during intervention and practicability. The secondary objective is to analyse the confirmation of reaching macroscopic tumor edges using intraoperative ultrasound or CT-scan, progression free survival, and overall survival during the entire study period.

Study design

This study is set up as an open label, prospective pilot study (Phase I study). The study will include 30 patients with gliomas, meningiomas, or brain metastasis in at the ErasmusMC brain tumor center. In all patients, the tumor will be operated conform standard procedure. Upon exposure of the tumor, a biopsy will be taken. Then one or a number of cryoprobes that will be required for tumor ablation will be inserted in the tumor. After proper positioning, the cryoablation will start. The ice formation will be monitored continuously, using cone-beam CT and/or intraoperative ultrasound. Prior to cryoprobe placement, there will be one scan. During cryoprobe placement, a variable number of scans may be necessary. After cryoprobe placement, there will be one scan to confirm the position. Additionally, there will be one scan during each freezing cycle (1 or 2 cycles per operation), and one scan after removing the cryoprobes. The duration of each freezing cycle will be a maximum of 10

minutes, followed by active thawing. After resection of the necrotic tumor, the patients will receive the standard treatment and follow up.

Intervention

See study design

Study burden and risks

All patients included in this study will receive the same (neo-)adjuvant therapy (if necessary) as patients who did not participate in this study. Depending on the size of the tumor, cryoablation takes approximately 30 minutes to complete. However, we expect that the total operating time will be considerably shorter as the cryoablation effect on the tumor should shorten the tumor resection time. Cryoablation is already used for the treatment of prostate carcinoma, kidney carcinoma and several lung cancers often with better results than other surgical treatments. Although only few clinical cases have been published, cryoablation seems not to increase complications or mortality rates in brain surgery.
Patient with brain tumors could benefit significantly from this therapy in terms of operation time and blood loss. Cryoablation could also potentially be used for non-resectable tumors or very vascularized tumors. Furthermore, the supposed immunological effect and opening of the blood-brain barrier could be very interesting in combination with adjuvant therapies in the future.
Regarding the use of cone-beam CT: by taking additional scans, the placement of cryoprobes can be even more precise, increasing the possibility of achieving a larger ablation zone. Additionally, cryoablation is often performed with the assistance of cone-beam CT in other pathologies. Considering the age (often 60+) and limited life expectancy of a significant portion of the patients (including glioma patients and patients with brain metastases), it can be assumed that the radiation burden is acceptable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age >18 years
2. Tumor suspected as glioma (1. Astrocytoma, IDH mutant 2. Oligodendroglioma, IDH-mutant and 1p/19q-codeleted 3. Glioblastoma, IDH-wildtype), meningioma (WHO gr. 1 and gr 2), or brain metastasis based on preliminary diagnosis for which the patient will undergo surgery
3. Supratentorial or infratentorial localization
4. Safe trajectory/trajectories possible for ablation of at least 70% of the tumor, avoiding eloquent structures
5. Karnofsky performance scale 70 or more
6. Sufficient knowledge of the Dutch language to understand the study documents (in the judgement of the attending physician or researcher)
7. Written Informed consent

Exclusion criteria

1. <18 years or >80 years
2. Tumor diameter bigger than 10 cm
3. Unsafe trajectory (eloquent structures could be damaged)
4. Pregnancy
5. Contra-indication for general anesthesia

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-07-2023
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	ICEfx Cryoablation system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	31-07-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-05-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL81429.078.22