MR-guided LITT therapy in patients with primary irresectable glioblastoma: a randomized pilot study

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In preparation of a randomized controlled trial, we aim to assess pilot data on technical feasibility and safety of LITT and to assess practical feasibility of a randomized study in patients with primary irresectable glioblastoma, as compared with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON55122

Source
ToetsingOnline

Brief title
EMITT-pilot study

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain cancer, glioblastoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Medtronic,Medtronic B.V.

Intervention

Keyword: Glioblastoma, Laser ablation

Outcome measures

Primary outcome

The main goal of the study is to assess technical feasibility and safety of LITT at our center and to assess practical feasibility of a future multicentre randomized controlled trial with the same design. Safety and technical feasibility will be assessed by an expert committee, consisting of head of department, independent expert and project leader.

To assess safety, the following endpoints will be considered:

- 30-days mortality

- Complications Clavien Dindo >/= 3

The procedure will be deemed feasible when:

- Time from inclusion to procedure
- Time from LITT to adjuvant therapy
- Surgical procedure duration between 4-8 h, comparable to a standard craniotomy for tumour resection

- Ablation of 90% of the target lesion in at least 70% of patients

To assess practical feasibility of a future larger randomized trial, the following parameters will be considered:

- Inclusion rate of patients meeting the inclusion criteria

- Withdrawal / drop-out within 30 days

- Completed follow-up at 3 months

Secondary outcome

Secondary endpoints of the study are:

- Overall and progression-free survival (OS, PFS) at 3 months after treatment

and change in quality of life (QoL) before and 3 months after treatment will be recorded and used to implement power analysis of a future randomized trial. No comparative statistical analysis will be performed in this pilot study on OS, PFS and QoL given the small amount of patients included.

- Tumour volume evolution on pre-operative, post-procedure and 3 months post-operative MRI.

- Learning curve (measured as evolution of duration of the intervention, ablation percentage and complications).

Study description

Background summary

Laser interstitial thermal therapy (LITT) has recently demonstrated its role as a safe and minimally invasive procedure in the treatment of brain tumours. Several studies show the application of LITT in newly diagnosed and recurrent glioblastoma, in radiotherapy and chemotherapy resistant metastases or in tumours in difficult accessible locations, with promising initial results. Due to limited follow-up and early experiences, there is currently no high-quality prospective evidence comparing LITT with standard of care, precluding any conclusions on cost-effectiveness of LITT.

Study objective

In preparation of a randomized controlled trial, we aim to assess pilot data on technical feasibility and safety of LITT and to assess practical feasibility of a randomized study in patients with primary irresectable glioblastoma, as compared with standard of care.

Study design

Prospective randomized pilot study.

Intervention

Patients will be randomized to receive either (i) biopsy and LITT (n=10) or (ii) biopsy only (n=10).

Study burden and risks

We hypothesize that LITT provides patients with an irresectable glioblastoma a relevant survival benefit with maximal retainment of quality of life at minimal morbidity and fast recovery. LITT has been shown to carry limited risk of post-operative complications, mostly reversible. The main risks associated to the procedure are bleeding, brain edema, neurological deterioration, operation site infection, epilepsy. Included patients will undergo cerebral follow-up MRI*s, following the same scanning protocol as currently used (before and 3 months after surgery). Patients will be requested to fill in two quality of life questionnaires (EQ-5D and EORTC QLQ - BN20) pre-operatively and 3 months after surgery.
All adverse events will be monitored.

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

- Informed consent, age >18-year-old
- Supratentorial localization
- Maximal volume <=70cc on post-contrast T1 MRI
- Safe trajectory/trajectories possible for ablation of at least 70% of the tumour, avoiding eloquent structures or transgression of a ventricle or vessel.
- Karnofsky Performance Status (KPS) >= 70

Exclusion criteria

- Contra-indication for general anaesthesia or MRI
- Lesion >70cc on post-contrast MRI on the day before intervention.
- Non-glioblastoma diagnosis as per frozen section analysis
- Pregnancy

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Visualase
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-09-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-02-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-09-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL73896.091.20