MR-guided LITT therapy in patients with primary irresectable glioblastoma: a multicenter randomized controlled trial

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To prospectively evaluate the (cost)-effectiveness of LITT plus chemoradiation therapy (CRT) vs. CRT alone in patients with primary irresectable glioblastoma (GBM).

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

Summary

ID

NL-OMON51323

Source
ToetsingOnline

Brief title
EMITT trial

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: Zorginstituut Nederland;Veelbelovende Zorg

Intervention

Keyword: LITT brain glioblastoma

Outcome measures

Primary outcome

The primary endpoints are overall survival (OS) and quality-of-life (QoL) using

QLQ-C30+BN20 questionnaire.

Secondary outcome

Secondary endpoints are disease-specific and progression-free survival (PFS),

generic QoL using EQ5D-5L, complication rates, tumor volume response, effects

on adjuvant treatment and costs.

Study description

Background summary

Laser interstitial thermal therapy (LITT) is recently growing as a 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. After conducting a pilot study at Radboudumc to study safety and feasibility of LITT in patients with an irresectable glioblastoma, we propose a larger nation-wide multicenter randomized controlled study to evaluate cost-effectiveness of this technique.

Study objective

To prospectively evaluate the (cost)-effectiveness of LITT plus chemoradiation therapy (CRT) vs. CRT alone in patients with primary irresectable glioblastoma (GBM).

Study design

Multicenter nation-wide randomized controlled trial.

Intervention

Patients will be randomized to receive either (i) biopsy and LITT, followed by standard CRT or (ii) biopsy alone, followed by standard CRT.

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, minimal morbidity and fast recovery. LITT has been shown to carry limited risk of post-operative complications, mostly reversible (5-26%). The main risks associated to the procedure are bleeding, brain edema, neurological deterioration, operation site infection, epilepsy. We recently conducted a pilot study at Radboudumc and the results showed the procedure to be safe and feasible. Patients will be followed for minimum 18 months, up to a maximum of 64 months over the entire study period..
All adverse events will be monitored

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Informed consent, age >18-year-old
- Supratentorial localization
- Safe trajectory/trajectories possible for ablation of at least 70% of the tumour, avoiding eloquent structures.
- Karnofsky Performance Status (KPS) >= 70

Exclusion criteria

- Contra-indication for general anaesthesia or MRI
- Non-glioblastoma diagnosis on pathology analysis
- No final pathology diagnosis available
- Pregnancy

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-04-2022

Enrollment:	238
Type:	Actual

Medical products/devices used

Generic name:	Visualase
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-03-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-06-2023
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	NL79202.091.21