

SCIENTIFIC LETTER

Eligibility assessment for yttrium-90 radioembolisation in patients with recurrent glioblastoma: A single-centre cohort study based on the FRONTIER clinical trial criteria (NCT05303467)



Evaluación de la elegibilidad de pacientes con glioblastoma recidivante para el tratamiento con radioembolización con itrio-90 según los criterios del ensayo clínico FRONTIER (NCT05303467)

Introduction

Glioblastoma (GBM) is the most common and aggressive primary malignant brain tumour in adults. Median survival following diagnosis is less than 15 months, and the two-year survival rate ranges between 26% and 33%.^{1,2} Standard treatment includes surgical resection, followed by temozolomide and radiotherapy, although recurrences are frequent.³

Endovascular radiotherapy with yttrium-90 (Y-90) microspheres is a promising treatment for patients with recurrent GBM, achieving high tumour response rates and fewer adverse effects in other target organs compared with other treatment modalities. In light of these advances, the FRONTIER clinical trial (NCT05303467) is currently being developed. This is the first in-human feasibility study (phase I) of the TheraSphere GBM Y-90 glass microsphere system.⁴

The purpose of this study is to determine the proportion of patients with recurrent GBM treated at a tertiary referral centre for oncological brain pathology who would be eligible for Y-90 radioembolisation according to the clinical and radiological criteria of NCT05303467.

Materials and methods

We carried out a retrospective analysis of a prospective database and included patients with histologically confirmed GBM between January and December 2019 at a tertiary referral centre. Recurrence was assessed by a multidisciplinary team, based on the Response Assessment in Neuro-Oncology (RANO) criteria applied to follow-up imaging studies and the patient's clinical condition. The

multidisciplinary neuro-oncology team included patients first according to the RANO criteria and then, according to the inclusion criteria of the FRONTIER clinical trial (NCT05303467).

The inclusion criteria of the FRONTIER clinical trial (NCT05303467)⁴ are as follows:

- GBM treated with surgical resection (complete/partial) followed by temozolomide in combination with radiotherapy (<60 Gy).
- Independent or partially dependent (requiring some assistance) for personal care and routine activities.
- Absence of multifocal or multicentric involvement.
- Absence of involvement of the dominant hemisphere, posterior fossa or critical subcortical structures.
- Absence of leptomeningeal involvement or extracranial metastatic disease.

Patients with imaging studies containing artifacts that precluded evaluation were excluded.

MRI scans of patients with recurrent GBM were subsequently analysed according to the angiographic inclusion criteria of the clinical trial to determine the final number of patients potentially eligible for inclusion in the FRONTIER clinical trial. The angiographic inclusion criteria are as follows:

- Tumour volume \leq 150 cc.
- Involvement of non-eloquent areas within the non-dominant hemisphere. Eloquent areas were defined as brain regions responsible for language production, vision, sensory function and motor function.
- Accessible neurovascular anatomy permitting safe microcatheter placement (in up to two feeding arteries).

Results

A total of 63 patients with histologically confirmed GBM at a tertiary referral centre for this condition between January and December 2019 were included (37 men; mean age 61 ± 11.32 years). Fig. 1 summarises the patient flowchart. A total of 49 patients were excluded for not meeting the clinical criteria.

Of the 14 patients eligible on clinical grounds, MRI scans of those with tumour recurrence were reviewed in accordance with the trial's angiographic inclusion criteria,