Glioma stem cell organoids: preclinical model of glioblastoma heterogeneity to explore resistance mechanisms to conventional treatment schedules.

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to establish primary patient derived organoid cultures from GM to study mechanisms that contribute to aggressive tumor growth and treatment resistance in primary and recurrent GM.

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

Summary

ID

NL-OMON44469

Source
ToetsingOnline

Brief title
Patient-derived glioma stem cell organoids.

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
glioma, Primary brain tumor

Research involving
Human

Sponsors and support

Primary sponsor: MAASTRO Lab

Source(s) of monetary or material Support: KWF grant Alpe D□Huzes PI M.Vooijs

Intervention

Keyword: Glioblastoma, Glioma stem cell, Organoid

Outcome measures

Primary outcome

Intra-and inter organoid genetic and epigenetic heterogeneity that is

representative for GM

Secondary outcome

Not applicable

Study description

Background summary

Glioblastoma (GM) is the most frequent incurable adult brain tumor with median survival of 15 months after diagnosis, despite extensive treatment with surgery, radiation therapy and chemotherapy. Tumor recurrence is inevitable after which life prolonging therapies are no longer available. The development of new treatments for GM is being hampered by inter-and intratumoral heterogeneity of tumors and their microenvironment, which currently cannot be predicted accurately with current diagnostics.

Study objective

to establish primary patient derived organoid cultures from GM to study mechanisms that contribute to aggressive tumor growth and treatment resistance in primary and recurrent GM.

Study design

Preclinical study, using patient derived glioblastoma tissue

Intervention

not applicable

Study burden and risks

Minimal burden: additional biopsies during a regular neurosurgical procedure (biopsy or debulking).
no benefit for the patient.

Contacts

Public
MAASTRO Lab

Doctor Tanslaan 12
Maastricht 6229 ET
NL
Scientific
MAASTRO Lab

Doctor Tanslaan 12
Maastricht 6229 ET
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• MRI imaging suggestive for glioblastoma
• > 18 years of age

Exclusion criteria

• Karnofsky index < 70
• Clotting disorders
• Neurosurgical contraindications for gross total resection

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-04-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	08-09-2017
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	02-10-2017
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	06-04-2020
Application type:	Amendment

Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	25-01-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL62648.096.17