Feasibility of standard therapy with temozolomide and radiotherapy combined with ketogenic diet in patients with glioblastoma multiforme

Published: 19-01-2015
Last updated: 19-03-2025

Primary objective:To assess the feasibility of KD in patients with glioblastoma multiforme during standard treatment.Secundary objectives:- To determine number of patients not being able to start protocol treatment (i.e. not able to reach ketosis,...

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

Summary

ID

NL-OMON40862

Source
ToetsingOnline

Brief title
Ketogenic therapy in patients with glioblastoma multiforme

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
Glioblastoma Multiforme

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Abbott,KWF: Alpe d'Huzes,Nutricia

Intervention

Keyword: Glioblastoma Multiforme, Ketogenic Diet

Outcome measures

Primary outcome

Feasibility of KD during standard treatment with RT and CT defined as successfully following the KD for 14 weeks after start of protocol treatment. So a patient is considered a failure for the primary endpoint if the KD is followed for less than 14 weeks from start of protocol treatment.

Secondary outcome

- Number of days on KD after start protocol treatment

- Compliance to the KD reflected in adequate and stable ketosis (3-4 mmol/l).

- Number of withdrawals or not reaching ketosis <3 mmol/L during the first 10 days of the KD

- Overall survival (OS) defined as time from diagnosis till date of death

- Progression free survival (PFS) defined as time from diagnosis till tumor progression or death (whichever comes first).

- Evaluation of neurological functioning will be evaluated by using the Vineland behavior scale (Appendix X) at baseline, after 8 weeks and at end of protocol treatment.

- Toxicity (i.e. adverse events CTCAE grade * 2).

Study description

Background summary

Previous research has shown that the use of ketogenic diet has two potentially beneficial effects in the treatment of cancer; the sensitization of tumor cells to the toxic effects of radiation and protection of normal tissues from the toxic side effects of chemotherapy.

Study objective

Primary objective:
To assess the feasibility of KD in patients with glioblastoma multiforme during standard treatment.

Secundary objectives:
- To determine number of patients not being able to start protocol treatment (i.e. not able to reach ketosis, or not being able to follow the KD for the first 10 days.
- To evaluate treatment effects in terms of overall survival (OS) and Progression free survival (PFS)
- To investigate the neurologic condition (on Vineland adaptive scale)

Study design

Phase I, open label, single center, non-randomized prospective feasibility study

Intervention

Addition of KD to standard treatment.

Study burden and risks

The standard treatment of GBM patients consists of tumor resection followed by combined RT and chemotherapy (CT) for a period of six weeks after surgery and subsequent monthly cycles of chemotherapy mostly during six months. During standard treatment the patient will receive KD during the study period of 14 weeks. The patient follows a strict diet with high fat and low carbohydrate content which induces ketosis. The patient will be closely monitored by a specialized dietitian and nurse practitioner. The patient related possible risks of the combination of standard treatment and KD are classified as low based on a previous explorative study performed elsewhere. During the 14weeks study period, safety and feasibility will be assessed by registering the adverse effects of standard treatment and KD, quality of life, protocol compliance and neurological functioning.

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

Part A:
- Histologically proven GBM (Astrocytoma WHO grade 4) after surgical resection
- Age * 18 years.
- Not dexamethasone dependent after surgery
- Amenable and planned for standard RT and CT and starting within 6 weeks after enrolment.
- Supportive partner or family member who can and is willing to help calculating, preparing and providing the meals.
- KPS *70.
- Written informed consent
- Able and willing to complete study specific diaries and questionnaires.
- Able to understand the procedures and instructions and able to give informed consent;Part B:

- Able to reach 3+ mmol/L ketosis within one week on the KD
- Abe to follow the KD during ketosis, for at least 3 days

Exclusion criteria

- Neurological deficit in language or cognitive functions causing inability to fully understand the study protocol and requirements
- Dementia or amnesia
- History of psychiatric disorder that would prohibit the understanding and giving of informed consent.
- The use of dexamethasone at time of registration
- Fatty acid disorders (like Medium Chain triglycerides disorders)
- Hypertriglyceridemia (> 10 mmol/L) despite treatment
- Hypercholesterolemia (> 7.5 mmol/L) despite treatment
- Alanine aminotransferase (ALAT) and aspartate aminotransferase (ASAT) >2.5x ULN
- (History of) Kidney stones
- Diabetes mellitus
- (History of) Pancreatitis
- Acute/chronic gastro-intestinal disease(s) such as persistent diarrhea, colitis ulcerosa and M. Crohn
- Underweight (BMI < 16)
- Overweight (BMI >30)
- Untreated or uncontrolled hypertension
- Any other chronic or systemic disease or serious medical condition (other than related to GBM), that may influence protocol compliance or outcomes of the study significantly

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2015

Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	19-01-2015
Application type:	First submission
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

ID: 19917
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50625.078.14
OMON	NL-OMON19917