# An evaluation of the tolerability and feasibility of combining 5-Amino-Levulinic Acid (5-ALA) with carmustine wafers (Gliadel) in the surgical management of primary Glioblastoma

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
21/06/2011		☐ Protocol		
Registration date 21/06/2011	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
14/05/2019	Cancer			

#### Plain English summary of protocol

http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-5ala-and-gliadel-wafers-as-part-of-treatment-for-glioblastoma-gala5

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Fiona Dungey

#### Contact details

Cancer Research UK & UCL Cancer Trials Centre 90 Tottenham Court Road London United Kingdom W1T 4TJ

# Additional identifiers

Clinical Trials Information System (CTIS)

2010-022496-66

ClinicalTrials.gov (NCT)

NCT01310868

Protocol serial number

# Study information

#### Scientific Title

An evaluation of the tolerability and feasibility of combining 5-Amino-Levulinic Acid (5-ALA) with carmustine wafers (Gliadel) in the surgical management of primary Glioblastoma (GALA-5 Trial)

#### Acronym

GALA-5

#### **Study objectives**

Glioblastoma (GBM) is the commonest brain tumour in adults. The combination of surgical cytoreduction (removal of the tumour), concomitant chemoradiation (chemotherapy given at the same time as radiotherapy) and adjuvant chemotherapy (chemotherapy given after the chemoradiotherapy leads to a median survival of 15 months and 2 year survival of 27%.

Aminolevulinic acid hydrochloride (5-aminolevulinic acid HCl; 5ALA; Gliolan) is a prodrug that leads to the selective accumulation of the fluorescent compound protoporphyrin IX (PPIX) in GBM. This can be visualised under blue light enabling objective surgical resection and improved progression free survival.

Carmustine wafers (Gliadel) are biodegradable copolymer discs impregnated with the alkylating agent carmustine that are implanted into the resection cavity at the end of surgery. They have a modest impact on survival of GBM patients but have yet to be evaluated in combination with fluorescence guided resection.

The aim of this study is to establish the safety, tolerability and feasibility of combining fluorescence-guided surgical tumour resection with intraoperative chemotherapy in GBM patients eligible to proceed onto chemoradiotherapy.

Patients with suspected primary GBM in whom complete resection is considered feasible will be given 5-ALA. They will then receive carmustine implants.

A protocol summary can be downloaded from the trial website: http://www.ctc.ucl.ac.uk/TrialDetails.aspx?TrialID=50

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx? StudyID=9566

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

10/H0304/100

#### Study design

Non-randomised interventional treatment trial

# Primary study design

Interventional

#### Study type(s)

**Treatment** 

#### Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Brain Tumour; Disease: Brain and Nervous System

#### **Interventions**

- 1. 60 patients are required to receive both Gliolan and Gliadel wafers for the trial
- 2. The trial will stop recruiting once 60 patients have received both treatments
- 3. The global sample size has been set at 120 patients on the portfolio to account for a 50% rate of failure to administer Gliadel wafers (e.g to patients with complications or those who are found to be ineligible during surgery)
- 4. 5-ALA (Gliolan) used to guide resection
- 5. Gliadel wafers are inserted into tumour cavity at the end of resection

#### Intervention Type

Drug

#### Phase

Phase II

#### Drug/device/biological/vaccine name(s)

Gliolan, Gliadel

#### Primary outcome(s)

- 1. % 5-ALA resected patients receiving Carmustine wafers
- 2. Post operative complication rate
- 3. No. patients with delay (> 6 weeks) to receiving chemoRT due to surgical complications
- 4. No. patients failing to receive chemoRT due to surgical complications
- 5. No. patients failing to complete chemoRT without interruption
- 6. % patients with a lower WHO performance status after surgery with Carmustine wafers

# Key secondary outcome(s))

- 1. Time to Clinical Progression
- 2. Survival at 24 months

# Completion date

01/05/2013

# Eligibility

#### Key inclusion criteria

- 1. The patient is reviewed at a specialist neuro-oncology multi-disciplinary team (MDT).
- 2. Preop MRI should be carried out, ideally on no or stable steroids according to RANO criteria
- 3. Imaging is evaluated by a neuro-radiologist and judged to have typical appearances of a primary GBM
- 4. Radical resection is judged to be realistic by the neurosurgeons at the MDT (i.e. NICE criteria for the use of Carmustine wafers can be met)

- 5. WHO performance status 0 or 1
- 6. Age ≥18
- 7. Patient judged by MDT to be fit for standard radical aggressive therapy for GBM (resection followed by RT with concomitant and adjuvant temozolomide)

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. GBM thought to be transformed low grade or secondary disease
- 2. The patient has not been seen by a specialist MDT.
- 3. There is uncertainty about the radiological diagnosis
- 4. 5-ALA or Carmustine wafers is contra-indicated (inc known or suspected allergies to 5-ALA or porphyrins, or acute or chronic types of porphyria)
- 5. Pregnant or lactating women
- 6. Known or suspected HIV or other significant infection or comorbidity that would preclude radical aggressive therapy for GBM
- 7. Active liver disease (ALT or AST ≥5 x ULRR)
- 8. Concomitant anti-cancer therapy except steroids
- 9. History of other malignancies (except for adequately treated basal or squamous cell carcinoma or carcinoma in situ) within 5 years
- 10. Previous brain surgery (including biopsy) or cranial radiotherapy
- 11. Platelets <100 x109/L
- 12. Mini mental status score <15

#### Date of first enrolment

01/05/2011

#### Date of final enrolment

01/05/2013

# Locations

#### Countries of recruitment

United Kingdom

England

# Study participating centre Cancer Research UK & UCL Cancer Trials Centre London United Kingdom W1T 4TJ

# Sponsor information

#### Organisation

University College London (UK)

#### **ROR**

https://ror.org/02jx3x895

# Funder(s)

#### Funder type

Charity

#### **Funder Name**

Cancer Research UK

#### Alternative Name(s)

CR UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Other non-profit organizations

#### Location

**United Kingdom** 

#### **Funder Name**

Samantha Dickson Brain Tumour Trust

#### Alternative Name(s)

The Samantha Dickson Brain Tumour Trust (SDBTT), SDBTT

#### **Funding Body Type**

Private sector organisation

# Funding Body Subtype

Other non-profit organizations

#### Location

United Kingdom

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
HRA research summary			28/06/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes