

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 21/06/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/06/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/05/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

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>

Study website

<http://www.ctc.ucl.ac.uk/TrialDetails.aspx?TrialID=50>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2010-022496-66

IRAS number

ClinicalTrials.gov number

NCT01310868

Secondary identifying numbers

9566

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/05/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

UK Sample Size: 120

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 $\geq 5 \times$ 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

England

United Kingdom

Study participating centre

Cancer Research UK & UCL Cancer Trials Centre

London

United Kingdom

W1T 4TJ

Sponsor information

Organisation

University College London (UK)

Sponsor details

Gower Street

London

England

United Kingdom

WC1E 6BT

Sponsor type

University/education

Website

<http://www.ucl.ac.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, 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)

SDBTT

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
HRA research summary			28/06/2023	No	No