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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/06/2011	**Overall study status** Completed	
Last Edited 14/05/2019	**Condition category** 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

Study website
http://www.ctc.ucl.ac.uk/TrialDetails.aspx?TrialID=50

Contact information

Type(s)
Scientific

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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 ≥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
England

United Kingdom

Study participating centre
Cancer Research UK & UCL Cancer Trials Centre
London
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Sponsor information

Organisation
University College London (UK)

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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