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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

Registration date
21/06/2011

Overall study status
Completed

Last Edited
14/05/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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

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

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	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes