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A phase I - II, prospective, double blind, randomised study of the safety and efficacy of sulfasalazine for the treatment of progressing malignant gliomas

Submission date
13/12/2005

Recruitment status
No longer recruiting

Registration date
15/12/2005

Overall study status
Completed

Last Edited
15/01/2010

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Pierre Robe

Contact details
University Hospital of Liege
University of Liege
Domaine du Sart Tilman B35
Liege
Belgium
4000
+32 (0)4 366 7209
pierre.robe@ulg.ac.be

Additional identifiers

Clinical Trials Information System (CTIS)
2004-004392-11

Protocol serial number
Ulg_GBM_04/1

Study information

Scientific Title

Study objectives
Recent evidence suggests that the transcription factor NF-kappaB is constitutively expressed in malignant gliomas and that its inhibition by drugs like sulfasalazine may block the growth of astrocytic tumours in vitro and in experimental models of malignant gliomas. The aim of this study is to evaluate the safety and efficacy of sulfasalazine as a treatment for progressive or recurring malignant gliomas.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The protocol was reviewed and approved by the Ethics Committee of the Faculty of Medicine of the University of Liège (IRB file number 2004/185). It also underwent review and approval by Belgian Federal Authorities (authorisation reference 548/03/05) and was granted the European Trial database (EudraCT) number 2004-004392-11.

Study design
A phase I - II, single centre, prospective, randomised, double blind clinical study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Progressive malignant glioma (astrocytic)

Interventions
The randomisation of patients between groups is provided by the Department of Statistics of the Faculty of Medicine of the University of Liège and the drug dosage is communicated only to the hospital pharmacist who prepares and delivers the drug. In order to facilitate the interim analysis of the data by the review committee, the randomisation algorithm was weighted so that 8 of the first 10 patients receive either the lowest or the highest drug dosage. Neither the investigators nor the patients are aware of the drug dosage that they provide/receive.

Sulfasalazine will be given orally three times a day at total doses of 1.5, 3, 4.5 or 6 g. Four capsules of the drug are to be taken with each meal. Sulfasalazine is to be taken continuously until radiological evidence of tumour progression, complete remission, or the development of serious or intolerable adverse effects. The patient may at any moment decide to discontinue his participation to the study, although every effort will be made to be able to carry on the follow-up. Finally, the independent review committee may decide at any moment to end the study based on safety issues.

Intervention Type

Drug

Phase
Phase I/II

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

Primary outcome(s)
1. The maximal daily oral dose of sulfaslazine that is tolerated by patients with recurrent or progressive malignant gliomas. Measurements will include the nature, frequency, possible causality and severity of adverse events that occur during treatment
2. The assessment of any clinical and/or radiological response of individual tumours to sulfasalazine

Key secondary outcome(s))
Overall and progression free survival following the initiation of sulfasalazine treatment.

Completion date
15/06/2007

Eligibility

Key inclusion criteria
1. Adult patients aged greater than 18 years
2. With recurrent or progressive World Health Organization (WHO) grade 3 or 4 astrocytic gliomas after surgery
3. Standard radiation therapy
4. A first line of conventional chemotherapy (e.g. temozolomide, CCNU or BCNU)

Recurrence or progression prior to inclusion are based on MacDonalds criteria. Patients are thoroughly informed about the nature of their disease, suspected prognosis, study background and objectives and potential alternative treatments. This information is provided both orally and in written form, prior to obtaining written informed consent from the patient.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Present with anaplastic oligodendroglioma (WHO grade 3)
2. Allergy to sulfa drugs
3. Porphyria
4. G-6-PD deficiency
5. Psychiatric disorder deemed incompatible with compliance to the study
6. Creatinine greater than 15 mg/l
7. Aspartate aminotransferase (TGO) greater than 200 UI/l
8. Amylase greater than 150 UI/l
9. Pregnant or lactating women
10. Patients may not have received any other experimental medication within 30 days (and at least five drug half-lives) prior to inclusion
11. Patients cannot concomitantly take mercaptopurine

Date of first enrolment
15/06/2005

Date of final enrolment
15/06/2007

Locations

Countries of recruitment
Belgium

Study participating centre
University Hospital of Liege
Liege
Belgium
4000

Sponsor information

Organisation
University of Liege, Department of Neurosurgery (Belgium)

ROR
https://ror.org/00afp2z80

Funder(s)

Funder type
Research organisation

Funder Name
Leon Frederic Fund (Belgium)

Funder Name
National Fund for Scientific Research (Belgium)

Results and Publications

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?
Results article	results	19/10/2009		Yes	No
Protocol article	Protocol	31/01/2006		Yes	No