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REO13 Brain - A study to evaluate the effects of intravenous injection of reovirus in patients prior to planned surgical removal of aggressive brain tumours that have relapsed, or tumours that have spread to the brain from elsewhere in the body.

Submission date 22/07/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/08/2012	**Overall study status** Completed	
Last Edited 12/08/2020	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-effects-drug-reolysin-people-cancer-affecting-brain-reo-13-brain

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R&D number: CO11/10054

Study information

Scientific Title
REO13 Brain: A clinical study to evaluate the biological effects of preoperative intravenous administration of wild-type reovirus (REOLYSIN®) in patients prior to surgical resection of recurrent high grade primary or metastatic brain tumours.

Study objectives
Intravenously injected wild-type reovirus (REOLYSIN®) can access recurrent high-grade primary or metastatic brain tumours in patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds East Ethics Committee, 04/09/2012

Study design
Open-label non-randomised interventional phase 1b clinical study

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Recurrent high-grade brain tumours and metastatic brain tumours

Interventions
Patients will be allocated to one of two groups:
Group A will be patients undergoing surgery for recurrent high grade primary brain tumours who require further debulking.

Group B will be patients planned for resection of brain metastases from any known solid tumour type. Patients will be enrolled in cohorts of 3 as follows.
In each group, the first 3 patients will have a single infusion of REOLYSIN on Day 1 only (cohort 1). The next 3 will have infusions on Days 1, 2 and 3 (cohort 2), and the final cohort of 3 will receive REOLYSIN on days 1 through 5. All doses of REOLYSIN will be at 1x10^10 TCID50, administered as a 1-hour IV infusion.

Intervention Type
Biological/Vaccine

Phase
Phase I

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

Primary outcome measure
Assessment for the presence of reovirus within recurrent high grade primary or metastatic brain tumours in patients by examination of the resected surgical specimen

Secondary outcome measures
1. Assessment of the replication and antineoplastic effects of reovirus in brain tumours
2. Assessment of the safety profile of REOLYSIN before surgery for brain tumours
3. Monitoring of the humoral and cellular immune response to REOLYSIN

Overall study start date
01/09/2012

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Male or female subjects with a diagnosis of recurrent high grade primary or secondary brain tumour, planned for surgical management
2. Have evidence of measurable or evaluable disease on standard of care imaging
3. Have NO continuing acute toxic effects of any prior radiotherapy, chemotherapy, or surgical procedures, i.e., all such effects must have resolved to Common Terminology Criteria for Adverse Events (CTCAE, Version 4.0) Grade ≤1. Radiotherapy/chemotherapy/surgery (except biopsies) must have occurred at least 28 days prior to study enrolment
4. Be at least 18 years of age
5. Have completed any previous systemic chemotherapy at least 4 weeks before entry into the study
6. Have an ECOG Performance Score of ≤ 1
7. Have a life expectancy of at least 1 month
8. Have baseline laboratory results at the time of consent as follows:
8.1. Absolute neutrophil count (ANC) ≥ 1.5 x 109 [SI units 109/L]
8.2. Platelets ≥ 100 x109 [SI units 109/L] (without platelet transfusion)
8.3. Haemoglobin ≥ 9.0 g/dL [SI units gm/L] (with or without RBC transfusion)

8.4. Serum creatinine ≤ 1.5 x upper limit of normal (ULN)
8.5. Bilirubin ≤ 1.5 x ULN
8.6. AST/ALT ≤ 2.5 x ULN
8.7. Negative serum pregnancy test for females of childbearing potential
9. Have signed an informed consent indicating that the patient is aware of the neoplastic nature of their disease and have been informed of the procedures of the protocol, the experimental nature of the therapy, alternatives, potential benefits, side effects, risks, and discomforts
10. Be willing and able to comply with scheduled visits, the treatment plan, and laboratory tests

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
At least 6 and up to 18

Key exclusion criteria
1. Receive concurrent therapy with any other investigational anticancer agent while on study
2. Patients on immunosuppressive therapy other than steroids, or known HIV infection or hepatitis B or C
3. Be a pregnant or breast-feeding woman. Female patients of childbearing potential must agree to use effective contraception, must be surgically sterile, or must be postmenopausal. Male patients must agree to use effective contraception or be surgically sterile. Barrier methods are a recommended form of contraception.
4. Have clinically significant cardiac disease (New York Heart Association, Class III or IV) including pre-existing arrhythmia, uncontrolled angina pectoris, myocardial infarction 1 year prior to study entry, or grade 2 or higher compromised left ventricular ejection fraction
5. Have dementia or altered mental status that would prohibit informed consent
6. Have any other severe, acute, or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or study drug administration or may interfere with the interpretation of study results and, in the judgment of the Principal Investigator, would make the patient inappropriate for this study

Date of first enrolment
01/09/2012

Date of final enrolment
31/08/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
St James's University Hospital
Leeds
United Kingdom
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Sponsor information

Organisation
University of Leeds (UK)

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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Brain Tumour Research and Support across Yorkshire [BTRS] (UK)

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