

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	☒ Prospectively registered ☐ Protocol
Registration date 28/08/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/08/2020	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

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

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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 1×10^{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(s)

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

Key secondary outcome(s)

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

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) $\geq 1.5 \times 10^9$ [SI units $10^9/L$]
 - 8.2. Platelets $\geq 100 \times 10^9$ [SI units $10^9/L$] (without platelet transfusion)
 - 8.3. Haemoglobin ≥ 9.0 g/dL [SI units gm/L] (with or without RBC transfusion)
 - 8.4. Serum creatinine $\leq 1.5 \times$ upper limit of normal (ULN)
 - 8.5. Bilirubin $\leq 1.5 \times$ ULN
 - 8.6. AST/ALT $\leq 2.5 \times$ 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre

St James's University Hospital

Leeds

United Kingdom

LS9 7TF

Sponsor information**Organisation**

University of Leeds (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration