

A phase I trial of figitumumab in children with relapsed/refractory solid tumour

Submission date 19/01/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/10/2017	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Kathy Pritchard-Jones

Contact details
The Institute of Cancer Research & Royal Marsden Hospital
Downs Road
Sutton
Surrey
United Kingdom
SM2 5PT
+44 (0)20 8661 3452
kathy.pritchard-jones@icr.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RG_09-071

Study information

Scientific Title

A phase I open label multicentre trial of figitumumab, an insulin-like growth factor 1 receptor (IGFR-1R) antibody, in children aged 1 - 12 years old with relapsed/refractory solid tumour

Acronym

FOREST

Study objectives

The aim of this study is to identify the maximum tolerated dose of figitumumab.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. UK: Trent Research Ethics Committee pending as of 15/06/2010
2. France: pending as of 15/06/2010

Study design

Phase I open-label multicentre 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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Relapsed/refractory solid tumours

Interventions

Figitumumab given on day 1 of a three weekly cycle as a 2.5 hour intravenous (IV) infusion. Starting dose 6 mg/kg with escalation cohorts that include 10 mg/kg, 20 mg/kg and 30 mg/kg.

In cycle one only, patients receive a second identical loading dose given on day 2.

Patients can receive up to 12 cycles of treatment providing there is clinical benefit. Follow up is up to 90 days after the last dose received or until the patient receives further therapy for their disease.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

Figitumumab

Primary outcome measure

Safety, measured by assessment of adverse events and laboratory abnormalities using Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 assessing grade timing, seriousness and relatedness. Outcome will be measured after cycle 1.

Secondary outcome measures

1. Pharmacokinetic blood sampling looking at plasma figitumumab concentrations, anti-drug antibodies, serum IGF-1/2, insulin-like growth factor binding protein 3 (IGFBP-3), insulin and growth hormone levels, measured Cycle 1 day 1, 2 and 8 and then prior to cycle 4. Antidrug antibodies measured cycle 1 day 1 and end of treatment.
2. Response to treatment measured by Response Evaluation Criteria In Solid Tumours (RECIST) criteria or by nuclear imaging or histology, measured every 2 cycles

Overall study start date

01/08/2010

Completion date

01/08/2012

Eligibility**Key inclusion criteria**

1. Aged greater than 1 years and less than 12 years, either sex
2. Histological confirmation of solid extra cranial malignancy at original diagnosis
3. Phase 2 cohort only: measureable or clinically evaluable disease
4. Current disease status must be one for which no available curative therapy
5. Performance status Lansky greater than 50% or Eastern Cooperative Oncology Group (ECOG) less than 2
6. Adequate recovery from major surgery prior to treatment
7. No mitral valve regurgitation greater than trivial as determined by Doppler echocardiogram. Shortening of fraction less than or equal to 29%. Electrocardiogram (ECG) should be normal.
8. Must have fully recovered from the acute toxic effects of all prior chemotherapy, immunotherapy, or radiotherapy. Two weeks from previous chemotherapy, four weeks from previous radiotherapy and six weeks from previous nitrosureas or myeloablative chemotherapy.
9. Adequate bone marrow function
10. Adequate renal function
11. Adequate liver function
12. Males or females of reproductive potential may not participate unless they agree to use an effective contraceptive method

13. All patients and/or their parents or legal guardians must sign a written informed consent
14. Patients and/or their parents and/or legal guardians must be willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures

Participant type(s)

Patient

Age group

Child

Lower age limit

1 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

24 - 48 depending on the dose escalation required

Key exclusion criteria

1. Concurrent treatment with any anti-tumour agents
2. Prior anti-IGF-1R therapy
3. Patients with symptomatic brain metastases
4. Significant active cardiac disease
5. Active infection
6. Poorly controlled Insulin-dependent diabetes mellitus
7. History of allergic reaction to immunoglobulin G (IgG)
8. Other severe acute or chronic medical or psychiatric condition

Date of first enrolment

01/08/2010

Date of final enrolment

01/08/2012

Locations**Countries of recruitment**

England

France

United Kingdom

Study participating centre

The Institute of Cancer Research & Royal Marsden Hospital
Surrey
United Kingdom
SM2 5PT

Sponsor information

Organisation

University of Birmingham (UK)

Sponsor details

Research & Commercial Services
Aitchison Building
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type

University/education

Website

<http://www.rcs.bham.ac.uk/>

ROR

<https://ror.org/03angcq70>

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

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