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

Submission date 19/01/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/06/2010	**Overall study status** Completed	
Last Edited 04/10/2017	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 recieve 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 (IGFCP-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 disase 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