

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

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

## Plain English Summary

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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 hypothesis

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

## Condition

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

## **Overall study end date**

01/08/2012

## **Eligibility**

### **Participant 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

**Participant 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

**Recruitment start date**

01/08/2010

**Recruitment end date**

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)**

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