ISRCTN29619083 https://doi.org/10.1186/ISRCTN29619083

# Can cancer cells be found and counted in blood samples from patients with bone sarcoma?

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|---|---|---|
| **Submission date**<br>05/06/2017 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>26/06/2017 | **Overall study status**<br>Completed | |
| **Last Edited**<br>15/03/2022 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**

Background and study aims
Bone sarcoma is a cancer that begins in the bone and is very rare. It affects any bones in the body but mainly the legs. This is an observational project recruiting patients with a suspected or confirmed diagnosis of bone sarcoma. Blood samples are obtained and sent to Newcastle University for identification of circulating tumour cells. The aim of this study is to evaluate the effectiveness of a blood sample assay for the detection and enumeration of circulating tumour cells in patients diagnosed with a bone sarcoma at several points during their treatment process.

Who can participate?
Patients with suspected or confirmed bone sarcoma (any gender or rage range 4 to 80)

What does the study involve?
Participants are approached to donate blood samples (up to 20ml) which are immediately transported to Newcastle University for analysis at diagnosis, after chemotherapy, after surgery, completion of treatment and relapse (if appropriate).

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
This study is being run by Newcastle University and takes place in hospitals in the UK.

When is the study starting and how long is it expected to run for?
May 2014 to March 2022

Who is funding the study?
1. Bone Cancer Research Trust (UK)
2. Children with Cancer UK (UK)

Who is the main contact?
Mr Kenneth Rankin
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# Contact information

### Type(s)
Public


### Contact name
Mr Kenneth Rankin

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# Additional identifiers

### Protocol serial number
18501

# Study information

### Scientific Title
Enumeration of circulating tumour cells in patients with bone sarcomas: an observational study

### Study objectives
The aim of this study is to evaluate the effectiveness of a blood sample assay for the detection and enumeration of circulating tumour cells in patients diagnosed with a bone sarcoma at several points during their treatment process.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
National Research Ethics Service Committee Yorkshire & The Humber - South Yorkshire, 24/12/2014, ref: 14YH/1314

### Primary study design
Observational

### Study design
Observational; Design type: Validation of outcome measures

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Sarcoma; UKCRC code/ Disease: Cancer/ Malignant neoplasms of bone and articular cartilage

### Interventions
Participants are approached to donate blood samples (up to 20ml) which are immediately transported to Newcastle University for analysis at the following time points:
1. At diagnosis
2. Following neo-adjuvant chemotherapy
3. Following surgery
4. Following adjuvant chemotherapy
5. At routine follow-up on completion of treatment
6. At relapse (if appropriate)

Total duration of observation and follow-up are the same at up to five years.

### Intervention Type
Other

### Primary outcome(s)
Enumeration of circulating tumour cells is assessed using flow cytometry at diagnosis, during treatment stages and on completion of treatment to assess for changes in the circulating tumour cell counts.

### Key secondary outcome(s)
1. Correlation of circulating tumour cell number measured by flow cytometry at diagnosis and subsequent treatment stages up to 5 years
2. Genomic analysis is undertaken using next generational sequencing at diagnosis and subsequent treatment stages up to 5 years

### Completion date
31/03/2022

## Eligibility

### Key inclusion criteria
1. Patients with a suspected bone sarcoma (any gender and age range 4 to 80 years old)
OR
2. Patients with a confirmed diagnosis of a bone sarcoma (any gender and age range 4 to 80 years old)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Patients (or their parent/guardian for those under the age of 16) who are unable to give informed consent
2. Prisoners
3. Patients who are pregnant

### Date of first enrolment
07/04/2015

### Date of final enrolment
31/07/2017

## Locations

### Countries of recruitment
United Kingdom

England

Scotland

### Study participating centre
**Freeman Hospital**
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

### Study participating centre
**Royal Victoria Infirmary**
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

### Study participating centre
**Royal Hospital for Sick Children**
9 Sciennes Road
Edinburgh

United Kingdom
EH9 1LF

**Study participating centre**
**University College London Hospitals**
Cancer Clinical Trials Unit
1st Floor East
250 Euston Road
London
United Kingdom
NW1 2PG

**Study participating centre**
**Birmingham Children's Hospital**
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

# Sponsor information

**Organisation**
The Newcastle Upon Tyne Hospitals NHS Foundation Trust

**ROR**
https://ror.org/05p40t847

# Funder(s)

**Funder type**
Charity

**Funder Name**
Bone Cancer Research Trust

**Funder Name**
Children with Cancer UK

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

## IPD sharing plan summary

Other

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version v1.3 | 15/04/2017 | 26/06/2017 | No | Yes |
| Participant information sheet | version v1.3 | 15/04/2017 | 26/06/2017 | No | Yes |