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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
05/06/2017		Protocol		
Registration date	Overall study status	Statistical analysis plan		
Last Edited Con-	Completed	Results		
	Condition category	Individual participant data		
	Cancer	<ul><li>Record updated in last year</li></ul>		

#### 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 kenneth.rankin@ncl.ac.uk

# Contact information

#### Type(s)

**Public** 

#### Contact name

Mr Kenneth Rankin

#### **ORCID ID**

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#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

#### Study design

Observational; Design type: Validation of outcome measures

#### Primary study design

Observational

#### Secondary study design

Cohort study

#### Study setting(s)

Hospital

#### Study type(s)

**Treatment** 

#### Participant information sheet

See additional files

#### 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 measure

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.

#### Secondary outcome measures

- 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

## Overall study start date

01/05/2014

#### 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** 

#### Age group

Adult

#### Sex

Both

#### Target number of participants

Planned Sample Size: 30; UK Sample Size: 30

#### 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

England

Scotland

United Kingdom

# 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

#### Sponsor details

Freeman Hospital
Freeman Road
High Heaton
Newcastle-Upon-Tyne
England
United Kingdom
NE7 7DN

#### Sponsor type

Hospital/treatment centre

#### **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**

#### Publication and dissemination plan

Planned publication date in a high-impact peer reviewed journal.

#### Intention to publish date

31/03/2018

#### 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