

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

Submission date 05/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/03/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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 age 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

Study design

Observational; Design type: Validation of outcome measures

Primary study design

Observational

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