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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
05/06/2017		<pre>Protocol</pre>		
Registration date 26/06/2017	Overall study status Completed	Statistical analysis plan		
		Results		
Last Edited 15/03/2022	Condition category Cancer	Individual participant data		
		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 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

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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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes