

Intracranial haemorrhage in thrombocytopenic haematology patients

Submission date 11/03/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 17/06/2011	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/07/2020	Condition category Haematological Disorders	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Intra-cranial haemorrhage (bleeding inside the skull) is the most serious type of bleed caused by a very low platelet count. Intra-cranial haemorrhage (ICH) is rare but can have devastating consequences, sometimes leading to death or long-term disability. It is not known why some patients with a very low platelet count bleed and others do not bleed. The main aim of this study is to identify possible risk factors for this type of bleeding. Other aims of the study are to look at the short-term outcomes for these patients (30 days after the ICH) and to produce a more accurate estimate of how often ICH occurs in this particular group of patients.

Who can participate?

Patients aged 16 or over with haematological disorders (typically those who have been diagnosed with cancer of the blood) who are being treated with chemotherapy or a stem cell transplant

What does the study involve?

Participating centres are sent monthly report cards for them to indicate if their centre has or has not observed any ICH that month. All information is completely anonymised (all personal identifiable data is removed) before being sent to the study team. No identifiable information is ever collected as part of this study. The study does not involve any active participation from patients. Information is collected about an event (the ICH) that has already occurred; it does not affect or influence treatment or care in any way.

What are the possible benefits and risks of participating?

Collecting and analysing anonymised information is a useful research method and can lead to a greater understanding of many aspects of healthcare in the longer term. As this data is collected anonymously and has no impact on any aspect of patient care there are no risks or benefits to any of the individual patients from whom the data is collected.

Where is the study run from?

NHS Blood and Transplant Clinical Trials Unit, Oxford (UK)

When is the study starting and how long is it expected to run for?
June 2011 to May 2015

Who is funding the study?
NHS Blood and Transplant (UK)

Who is the main contact?
Dr Lise J Estcourt
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
CTCP 10-02

Study information

Scientific Title
Risk factors of intracranial haemorrhage in thrombocytopenic haematology patients: a case-control study

Acronym
INCITE

Study objectives
To advance the quality of care for haematology patients it is important to gain a greater understanding of the risk factors for life-threatening haemorrhage. This case-control study concentrates on intracranial haemorrhage because it is the most serious type of bleed caused by

significant thrombocytopenia. If it does not cause death it may lead to significant long-term morbidity. However, this complication of thrombocytopenia is rare, its exact incidence is uncertain and pre-disposing risk factors are unknown.

Protocol can be found at: http://hospital.blood.co.uk/library/pdf/InCiTe_Study_Protocol.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oxford REC B, 16/02/2011, ref: 10/H0605/78

Primary study design

Observational

Study design

Case control study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Intracranial haemorrhage in patients with haematological malignancies

Interventions

Case-control study with prospective active surveillance of cases

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Factors (e.g., age, type of haematological disease, treatment, infection) associated with an increased risk of developing an intracranial haemorrhage

Key secondary outcome(s)

1. Incidence of intracranial haemorrhage in thrombocytopenic haematology patients
2. Short-term outcomes for these patients (e.g., death or persistent neurological deficit)
3. Rates of death
4. Rates of significant neurological deficits

Completion date

01/05/2015

Eligibility

Key inclusion criteria

1. All thrombocytopenic adult haematology patients in the UK undergoing intensive chemotherapy (defined as chemotherapy expected to cause a significant thrombocytopenia $< 50 \times 10^9/L$ for > 5 days) or a stem cell transplant who had an intracranial haemorrhage within the study period
2. Aged 16 years or older
3. Only patients being treated with curative intent
4. All severities of intracranial haemorrhage
5. All types of intracranial haemorrhage

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

01/05/2011

Date of final enrolment

01/05/2015

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

John Radcliffe Hospital

Oxford

United Kingdom

OX3 9BQ

Sponsor information

Organisation

National Health Service Blood and Transplant (NHSBT) (UK)

ROR

<https://ror.org/0227qpa16>

Funder(s)**Funder type**

Government

Funder Name

National Health Service Blood and Transplant (NHSBT) (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/02/2014		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes