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Intracranial haemorrhage in thrombocytopenic haematology patients

Submission date
11/03/2011

Recruitment status
No longer recruiting

Registration date
17/06/2011

Overall study status
Completed

Last Edited
24/07/2020

Condition category
Haematological Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
lise.estcourt@nhsbt.nhs.uk

Study website
http://hospital.blood.co.uk/research/incite_study/index.asp

Contact information

Type(s)
Scientific

Contact name
Dr Lise Estcourt

Contact details
NHS Blood and Transplant
Level 2
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9BQ
-
lise.estcourt@nhsbt.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Case control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/05/2011

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 x 10E9/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

Age group
Adult

Sex
Both

Target number of participants
Dependent on true incidence of intracranial haemorrhage within the study population. Minimum of 78 cases and 78 controls. As of 23/09/2013, the trial is still actively recruiting patients.

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
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9BQ

Sponsor information

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

Sponsor details
c/o Professor Marion Scott
NHS Blood and Transplant
Southmead Road
Bristol
United Kingdom
BS10 5ND

Sponsor type
Government

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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