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A randomised controlled trial of prophylactic versus no-prophylactic platelet transfusions in patients with haematological malignancies

Submission date
31/07/2006

Recruitment status
No longer recruiting

Registration date
12/09/2006

Overall study status
Completed

Last Edited
24/01/2022

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-platelet-transfusions-during-treatment-for-cancer-of-the-blood-or-lymphatic-system

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PG04/5

Study information

Scientific Title
A randomised controlled trial of prophylactic versus no-prophylactic platelet transfusions in patients with haematological malignancies

Acronym
TOPPS

Study objectives
The trial hypothesis is that a policy of no prophylactic platelet transfusion is as safe as (or non-inferior to) a policy of prophylactic transfusion, based on a threshold peripheral blood platelet count of less than 10 x 10^9/L.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study was awarded ethics committee approval on 15/03/2006, REC ref: 06/Q1606/8

Study design
Randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Haematological malignancies

Interventions
Eligible patients will be randomised to receive either prophylactic platelet transfusions if the platelet count is less than 10x10^9/L, or no prophylaxis with therapeutic transfusions given only after documented signs or symptoms of bleeding.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
The percentage of patients who develop a WHO Grade two, three or four bleeding event up to 30 days from randomisation

Secondary outcome measures
These will follow the same strategy as for the primary outcome using regression modelling techniques to adjust for the three stratifying factors. In particular:
1. Logistic regression for proportion developing grade 3 or 4 bleed - subsidiary outcome measure:
1.1. Cox proportional hazards regression model for time to first WHO grade two, three, or four bleed
1.2. Time from randomisation to second grade two bleed
1.3. Period in hospital
1.4. Poisson regression for the rate of bleeding events

Descriptive analyses will be presented for other outcomes.

Overall study start date
07/07/2006

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. They are aged 16 years or over
2. They have a confirmed diagnosis of a haematological malignancy
3. They are receiving or are going to receive myelosuppressive chemotherapy on this hospital admission with or without haematopoietic stem cell support (this includes patients undergoing haemopoietic stem cell transplantation - autograft or allograft)
4. They are thrombocytopenic or expected to become thrombocytopenic with a platelet count of less than 50 x 10^9/L for at least five days
5. They are able to comply with treatment and monitoring

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600

Key exclusion criteria
1. They have had a World Health Organization (WHO) Grade three or four bleed (refer to Modified WHO Bleeding Criteria) during any stage of their treatment to date
2. During the current admission, they have experienced or are currently experiencing a WHO Grade two or greater bleed
3. They have any inherited clotting disorder (e.g. haemophilia)
4. They need to remain on regular aspirin (or related drugs), or will require regular therapeutic doses of anticoagulants (heparin), during the whole period of thrombocytopenia
5. They have acute promyelocytic leukaemia
6. They have known HLA antibodies
7. They are pregnant
8. They have previously been randomised in this trial at any stage of their treatment

Date of first enrolment
07/07/2006

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
National Blood Service
Oxford
United Kingdom
OX3 9BQ

Sponsor information

Organisation
The National Blood Service (UK)

Sponsor details
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Sponsor type
Research organisation

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Research organisation

Funder Name
National Blood Service (UK) - NBS National Research Review Committee approval

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/05/2013		Yes	No
Results article	cost analysis results	01/10/2014		Yes	No
Results article	subgroup analysis results	01/10/2014		Yes	No
Results article	results	01/06/2015		Yes	No
Results article		01/09/2021	10/11/2021	Yes	No
Plain English results			24/01/2022	No	Yes