

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/01/2022	Condition category Cancer	<input type="checkbox"/> 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

Protocol serial number

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 $10 \times 10^9/L$.

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

Primary study design

Interventional

Study design

Randomised controlled study

Study type(s)

Treatment

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 $10 \times 10^9/L$, or no prophylaxis with therapeutic transfusions given only after documented signs or symptoms of bleeding.

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

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

Key secondary outcome(s)

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.

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 $50 \times 10^9/L$ for at least five days
5. They are able to comply with treatment and monitoring

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre**National Blood Service**

Oxford

United Kingdom

OX3 9BQ

Sponsor information

Organisation

The National Blood Service (UK)

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

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