ISRCTN43616311 https://doi.org/10.1186/ISRCTN43616311

Transfusion Effects of Myelodysplastic Patients: Limiting Exposure

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/09/2017	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Transfusion Effects of Myelodysplastic Patients: Limiting Exposure

Acronym
TEMPLE study

Study objectives
1. There is no difference in Health Related Quality of Life (HRQoL) using a Haemoglobin (Hb) transfusion trigger of 7.2 g/dl compared to Hb transfusion trigger of 9.6 g/dl
2. A Hb transfusion trigger of 7.2 g/dl leads to a diminished use of Red Blood Cell (RBC) transfused compared to a Hb transfusion trigger of 9.6 g/dl
3. A Hb transfusion trigger of 7.2 g/dl leads to a decrease in the development of RBC allo-antibodies

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre, randomised, single blind, active controlled, parallel group trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Myelodysplastic Syndrome (MDS)

Interventions
Red blood cell transfusion.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Fatigue.

Secondary outcome measures
1. Health Related Quality of Life (HRQoL)
2. Blood usage and the costs
3. Haemoglobin increase after transfusion
4. Heart beat, blood pressure, temperature, platelet count
5. Development of RBC alloantibodies
6. Mortality

Overall study start date
10/02/2002

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Diagnosis myelodysplastic syndrome (primary or secondary) based on cytopenia in at least 1 cell line and dysplasia in 2 cell lines (and no other cause [especially deficiencies]) and a pathologic anatomic diagnosis after bone marrow punction
2. Refractory Anaemia (RA):
2.1. Blood: less than or equal to 1% blasts, less than or equal to 1 x 10^9 monocytes
2.2. Bone marrow: less than 5% blasts, ringed sideroblasts less than or equal to 15% of the erythroid cells
3. Refractory Anaemia with Ringed Sideroblasts (RARS):
3.1. Blood: less than or equal to 1% blasts, less than or equal to 1 x 10^9 monocytes
3.2. Bone marrow: less than 5% blasts, ringed sideroblasts greater than 15% of the erythroid cells
4. Refractory Anaemia with Excess Blasts (RAEB):
4.1. Blood: less than 5% blasts, less than or equal to 1 x 10^9 monocytes
4.2. Bone marrow: blasts greater than or equal to 5% to less than or equal to 20%
5. Chronic Myelomonocytic Leukaemia (CMML):
5.1. Blood: greater than 1 x 10^9/l monocytes, less than 5% blasts
5.2. Bone marrow: blasts less than 20%, increase of the monocytic component
6. Erythrocyte transfusion need
7. Working knowledge of the national language
8. Written consent for participating this study (informed consent)

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Candidate for bone marrow or organ transplantation
2. Medication: growth factors (Granulocyte Monocyte Colony Stimulating Factor [GM-CSF]), or Erythropoietin (EPO)
3. Patients who will receive an intensive chemotherapeutic treatment with a cytopenia, expected longer than 2 weeks
4. Refractory anaemia with excess blasts in transformation (RAEB-t):
4.1. Blood: 5% blasts or Auer rods
4.2. Bone marrow: or blasts greater than 20% to less than 30% or Auer rods
5. Pregnancy at the moment of inclusion
6. Patients with congenital severe haemolytic anaemia, like thalassemia or sickle cell anaemia
7. Patients with Acquired Immune Deficiency Syndrome (AIDS) or a severe congenital or acquired (e.g., iatrogenic) immunological disorder
8. Severe active infections at the moment of inclusion
9. Severe cardiac, pulmonal, neurological, metabolic or psychiatric disease at the moment of inclusion

Date of first enrolment
10/02/2002

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Sanquin Blood Bank South West Region
Rotterdam
Netherlands
3015 CN

Sponsor information

Organisation
Sanquin Blood Bank South West Region (The Netherlands)

Sponsor details
Wytemaweg 10
Rotterdam

Netherlands
3015 CN

Sponsor type
Research organisation

Website
http://www.sanquin.nl/sanquin-nl/sqn_home_nl.nsf

ROR
https://ror.org/01fm2fv39

Funder(s)

Funder type
Government

Funder Name
The Netherlands Ministry of Health, Welfare and Sport (The Netherlands)

Funder Name
National Institute of Public Health and Environmental Protection (RIVM) (The Netherlands)

Funder Name
Friends of the Blood Transfusion Foundation (Stichting Vrienden van de Bloedtransfusie) (The Netherlands)

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?
Results article	results	01/04/2003		Yes	No