Temple study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24147

Source
NTR

Brief title
Temple study

Health condition

MDS patients

Sponsors and support

Primary sponsor: Sanquin Blood Bank South West Region
Sanquin Blood Bank South West Region
Wytemaweg 10
3015 CN Rotterdam
The Netherlands
Tel: 0031 10-4630630
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E-mail: dick.van.rhenen@bloodrtd.nl
Source(s) of monetary or material Support: National Institute of Health (Ministerie van VWS
Stichting Vrienden van de Bloedtransfusie

Intervention

Outcome measures

Primary outcome

Fatigue.

Secondary outcome

1. Health related Quality of Life;

2. Blood usage and the costs;

3. Haemoglobin increase after
transfusion;

4. Hart beat, blood pressure, temperature, platelet count;

5. Development of RBC alloantibodies;

6. Mortality.

Study description

Background summary

N/A

Study objective

1. There is no difference in HRQoL using a Hb transfusion trigger of 7.2 gr/dl compared to Hb transfusion trigger of 9.6 gr/dl;

2. A Hb transfusion trigger of 7.2 gr/dl leads to a diminished use of RBC transfused compared to a Hb transfusion trigger of 9.6 gr/dl;

3. A Hb transfusion trigger of 7.2 gr/dl leads to a decrease in the development of RBC allo antibodies.

Study design

N/A

Intervention

Red blood cell transfusion.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosis myelodysplastic syndrome (primary or secondary) based on cytopenia in at least 1 cell line + dysplasia in 2 cell lines (and no other cause (especially deficiencies)) and a pathologic anatomic diagnosis after bone marrow punction;

2. Refractory anaemia (RA): blood: ¡Ü 1% blasts, ¡Ü 1 x 109 monocytes; bone marrow: < 5% blasts, ringed sideroblasts ¡Ü 15% of the erythroid cells;

3. Refractory anaemia with ringed sideroblasts (RARS): blood: ¡Ü 1% blasts, ¡Ü 1 x 109 monocytes; bone marrow: < 5% blasts, ringed sideroblasts > 15% of the erythroid cells;

4. Refractory anaemia with excess blasts (RAEB): blood: < 5% blasts, ¡Ü 1 x 109 monocytes; bone marrow: blasts ¡Ý 5 -¡Ü 20%;

5. Chronic myelomonocytic leukaemia (CMML): blood: >1 x 109/l monocytes, <5% blasts; bone marrow: blasts < 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).

Exclusion criteria

1. Candidate for bone marrow- or organ transplantation;

2. Medication: growth factors (GM-CSF), or 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): blood: ¡Ý 5% blasts or Auer rods; bone marrow: or blasts > 20 - < 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 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-02-2002
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	10-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL296
NTR-old	NTR334
Other	: N/A
ISRCTN	ISRCTN43616311

Study results

Summary results
British Journal of Haematology 2003;121(2):270-274

NVB Bulletin oktober 2002;3:2-5

Nederlands Tijdschrift voor Klinische Chemie 2003; 28: 280-284.