

# Transfusion Effects of Myelodysplastic Patients: Limiting Exposure

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/09/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**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 puncture
2. Refractory Anaemia (RA):
  - 2.1. Blood: less than or equal to 1% blasts, less than or equal to  $1 \times 10^9$  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  $1 \times 10^9$  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  $1 \times 10^9$  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  $1 \times 10^9$ /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](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?
<a href="#">Results article</a>	results	01/04/2003		Yes	No