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# 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

## 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

### Primary study design
Interventional

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

### Study type(s)
Treatment

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

### Interventions
Red blood cell transfusion.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
Fatigue.

### Key secondary outcome(s)
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

### 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

## Healthy volunteers allowed
No

## Age group
Not Specified

## Sex
All

## 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)

**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

## 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 |