Transfusion as supportive care for the improvement of the quality of life.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20749

Source
NTR

Health condition

Patiënts with a chronic need for bloodtransfusion due to e.g. myelodysplatic syndrome, myelofibrosis or myeloproliferative conditions.

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Postbus 50.000
7500 KA Enschede
tel. 053 487 2000
The Netherlands
Source(s) of monetary or material Support: Tekke Huizinga Fonds

Intervention

Outcome measures

Primary outcome

Quality of life assesed with the EORTC QLQ C-30 questionnaire.

Secondary outcome

1. Number of transfusion units;

2. Transfusionfrequency;

3. Average Hb concentration before transfusion;

4. Number and duration of hospital visits.

Study description

Background summary

Improvement or maintaining quality of life is an important goal for patients that receive supportive care as their sole treatment. Blood transfusion can be considered as supportive care for patients with chronic anemia. Patients receive a blood transfusion if their Hb concentration is below 5.0 mmol/l. Under the current protocol, patients receive 2 units of packed cells per transfusion. Patients indicate that they feel better, however there are no objective data available on the quality of life, the optimal transfusion trigger and the quantity of packed cells needed to improve the patients well being. Due to the administration of 2 units of packed cell at every blood transfusion, large fluctuations in Hb concentration occur. This might increase the need for blood transfusions and affect the average quality of life.

Our hypothesis is that patients will feel better is their Hb concentration is maintained at a relative constant level and that the transfusion trigger can be lowered on asymptomatic patients.

Patients receiving blood transfusion as supportive care will be approached for this study. Upon enrollment, patients will be randomized in two groups:

1. Standard group undergoing the current protocol of 2 units of packed cells/transfusion;

2. Intervention group will receive only 1 unit of packed cells/transfusion.

The quality of life will repeatedly be assessed by a questionnaire, secondary measurements consist of average Hb concentration, frequency of transfusions en visits to the hospital etc.

Our patients will be recruited initially from Medisch Spectrum Twente, Enschede, the Netherlands.

Study objective

A constant Hb concentration will improve the quality of life of patiënts with a chronic need for bloodtransfusions.

Study design

1x/3 months questionnaire concerning quality of life.

Intervention

Transfusion with either:

1. 1 erythrocyte concentrate;

2. 2 erythrocyte concentrate.

Contacts

Public
Medisch Spectrum Twente
Postbus 50.000
A.W. Duyts
Enschede 7500 KA
The Netherlands
+31 (0)53 4872000
Scientific
Medisch Spectrum Twente
Postbus 50.000
A.W. Duyts
Enschede 7500 KA
The Netherlands
+31 (0)53 4872000

Eligibility criteria

Inclusion criteria

1. Need for chronic transfusion;

2. 18-85 years;

3. Patient is fully competent;

4. Written informed consent.

Exclusion criteria

1. Chemotherapy;

2. Extra-medullary hematopoiesis;

3. Language barrier.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-01-2011
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	NL2293
NTR-old	NTR2684
Other	METC Medisch Spectrum Twente Enschede : P10-36
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A