

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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20749

Bron

NTR

Aandoening

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

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente

Postbus 50.000

7500 KA Enschede

tel. 053 487 2000

The Netherlands

Overige ondersteuning: Tekke Huizinga Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 if 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.

Doel van het onderzoek

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

Onderzoeksopzet

1x/3 months questionnaire concerning quality of life.

Onderzoeksproduct en/of interventie

Transfusion with either:

1. 1 erythrocyte concentrate;
2. 2 erythrocyte concentrate.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Need for chronic transfusion;
2. 18-85 years;
3. Patient is fully competent;
4. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Chemotherapy;
2. Extra-medullary hematopoiesis;
3. Language barrier.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	05-01-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2293
NTR-old	NTR2684
Ander register	METC Medisch Spectrum Twente Enschede : P10-36
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A