REMOTE 2

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Transfusing these patients to a higher hemoglobin level will increase their cognition, activity and decrease the average heart rate.

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

Samenvatting

ID

NL-OMON23694

Bron
NTR

Verkorte titel
REMOTE 2

Aandoening

MDS, MPN

Ondersteuning

Primaire sponsor: non
Overige ondersteuning: TRIP transfusie en transplantatiereacties in patiënten and LUMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Heart rate

Toelichting onderzoek

Achtergrond van het onderzoek

24 transfusion dependent MDS/MPN patients receive 3 different amounts of RBC transfusion (Standard of Care(SoC) amount, SoC+1 and SoC+2). Continuous heart rates and activity parameters are monitored using a smartwatch, cognitive and QoL parameters are measured with web-based tests/questionnaires.

Doel van het onderzoek

Transfusing these patients to a higher hemoglobin level will increase their cognition, activity and decrease the average heart rate.

Onderzoeksopzet

0) Baseline demographics

Continuously(during each study transfusion cycle): heart rate and activity parameters with withings steel HR smartwatch

First study transfusion
1) 1-3 days before study transfusion: QUALMS and MFI questionnaires; CANTAB Cognitive tasks: RVP SWM and OTS; Heart rate and bloodpressure with Withings BPM connect; Hemoglobin level.
2) directly after study transfusion: Hemoglobin level
3) 2-4 days after study transfusion: QUALMS and MFI questionnaires; CANTAB Cognitive tasks: RVP SWM and OTS; Heart rate and bloodpressure with Withings BPM connect;
4) 1-3 days before next transfusion: QUALMS and MFI questionnaires + questionnaire on experience of last transfusion; CANTAB Cognitive tasks: RVP SWM and OTS; Heart rate and bloodpressure with Withings BPM connect;

Second study transfusion
5) 1-3 days before study transfusion: QUALMS and MFI questionnaires; CANTAB Cognitive tasks: RVP SWM and OTS; Heart rate and bloodpressure with Withings BPM connect; Hemoglobin level.
6) directly after study transfusion: Hemoglobin level
7) 2-4 days after study transfusion: QUALMS and MFI questionnaires; CANTAB Cognitive tasks: RVP SWM and OTS; Heart rate and bloodpressure with Withings BPM connect;
8) 1-3 days before next transfusion: QUALMS and MFI questionnaires+ questionnaire on experience of last transfusion; CANTAB Cognitive tasks: RVP SWM and OTS; Heart rate and bloodpressure with Withings BPM connect;

third study transfusion
9) 1-3 days before study transfusion: QUALMS and MFI questionnaires; CANTAB Cognitive tasks: RVP SWM and OTS; Heart rate and bloodpressure with Withings BPM connect;

Hemoglobin level.
10) directly after study transfusion: Hemoglobin level
11) 2-4 days after study transfusion: QUALMS and MFI questionnaires; CANTAB Cognitive tasks: RVP SWM and OTS; Heart rate and bloodpressure with Withings BPM connect;
12) 1-3 days before next transfusion: QUALMS and MFI questionnaires+ questionnaire on experience of last transfusion; CANTAB Cognitive tasks: RVP SWM and OTS; Heart rate and bloodpressure with Withings BPM connect;

Onderzoeksproduct en/of interventie

+1 or +2 RBC's at a transfusion episode, control: normal number of RBC's

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

MDS or MDS/MPN, transfusion dependent. >18 years old.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- significant cardiac, pulmonary of renal failure.

- recent change of therapy that might influence the transfusion need.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices). Other documents that will be available are the study plan and statistical analysis plan. Data will be availaible following publication, no end date. It will be shared with researchers who provide a methodologically sound proposal to achieve aims in the approved proposal. The data will be available in our University's data warehouse but without investigator support other than deposited metadata.

Ethische beoordeling

Positief advies

Datum:	10-02-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52859
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9289
CCMO	NL73847.058.20
OMON	NL-OMON52859

Resultaten