REMOTE 2

No registrations found.

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

Summary

ID

NL-OMON23694

Source
NTR

Brief title
REMOTE 2

Health condition

MDS, MPN

Sponsors and support

Primary sponsor: non
Source(s) of monetary or material Support: TRIP transfusie en transplantatiereacties in patiënten and LUMC

Intervention

Outcome measures

Primary outcome

Heart rate

Secondary outcome

Cognition, activity, QoL

Study description

Background summary

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.

Study objective

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

Study design

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;

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- significant cardiac, pulmonary of renal failure.
- recent change of therapy that might influence the transfusion need.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2021
Enrollment:	24
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
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.

Ethics review

Positive opinion

Date:	10-02-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52859
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results