Comparison of different transfusion strategies for red blood cell transfusion dependent MDS and MPN patients - a cross-over study with remote patient monitoring

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Compare the effect of three different RBC transfusion strategies* (Standard of care (SoC), SoC+1 and SoC+2**) on heart rate in a population of chronically transfused patients (with on average at least 1 RBC transfusion each 8 weeks as personal...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anaemias nonhaemolytic and marrow depression
Study type	Interventional

Summary

ID

NL-OMON52859

Source
ToetsingOnline

Brief title
REMOTE 2

Condition

- Anaemias nonhaemolytic and marrow depression

Synonym
chronic anemia, MDS

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: TRIP

Intervention

Keyword: MDS, Quality of life, Transfusion, Wearables

Outcome measures

Primary outcome

Difference in heartrate pre- and posttransfusion as measured by the Withings

BPM connect

Secondary outcome

Quality of life

cognition

activity

Study description

Background summary

There are no completed trials in the outpatient setting comparing restrictive vs. liberal transfusion strategies for transfusion-dependent hemato-oncologic patients. Moreover, there is little data in general about the value of outpatient transfusions.
In order to optimize red cell transfusion in RBC transfusion-dependent patients both the risks and the benefits should be known and carefully weighted. The results of trials conducted in other patient groups (surgical and ICU patients) indicated that RBC transfusion may have a negative impact on patient outcome and therefore a restrictive transfusion strategy is recommended for these groups of patients. Hardly any research, however, has been done in chronically transfusion dependent patients. A restrictive transfusion policy may be less optimal for this patient category since the goal of the transfusion is the improvement of the quality of life (QOL), rather than survival or vital support as in the critical ill. QoL, however, is hard to substantiate and a patient specific parameter. To understand the full balance between risks and benefits

of a red cell transfusion policy in RBC transfusion dependent patients, we need to assess objective clinical relevant outcomes including QoL. While so far QoL was quantified by questionnaire based scoring, nowadays wearable artificial intelligence (AI) technology might add objective parameters like transfusion modulation on physical, cardio-pulmonary activity and cognition to the QoL equation.

Current standard of transfusion care in transfusion-dependent patients is based on a restrictive Hb trigger-based policy for regular RBC transfusions, which typically includes multiple (2-4) units every 2-4 weeks. As said, clinically relevant endpoints such as QOL and cognition, are currently not taken into account when the decision to give a transfusion is made. Patient vital signs and functional activity are more patient specific transfusion indicators and, therefore, may enable personalized timing and dosing of RBC transfusion. To date, however, no published randomized trials have examined the impact of different RBC transfusion policies on functional outcomes in chronic recipients of RBC transfusions, since continuous monitoring in the outpatient setting was not possible. Nowadays, wearables can effectively collate vital signs and functional activity after transfusion and this could result in an optimal transfusion policy for any individual patient without a significant change in overall healthcare costs, but better overall individual quality of life.

after completion of the first 12 patients we will do an interim analysis. To account for the increased risk of Type I error due to multiple testing, the threshold for statistical significance will be halved.

Study objective

Compare the effect of three different RBC transfusion strategies* (Standard of care (SoC), SoC+1 and SoC+2**) on heart rate in a population of chronically transfused patients (with on average at least 1 RBC transfusion each 8 weeks as personal standard of care).
Secondary:
- Compare the effect of three different RBC transfusion strategies* (Standard of care (SoC), SoC+1 and SoC+2**) on physical activity, QoL and cognition in a population of chronically transfused patients (with on average at least 1 RBC transfusion each 8 weeks as personal standard of care).
- Compare QoL by questionnaires with wearable based cognition, vital and physical activity parameters and their correlation with transfusion induced Hb-level changes.

** An exception will be made for those patients that normally receive 3 or more RBC's as SoC. To prevent circulatory overload, instead of +2 RBC's, they will receive one RBC less than their SoC.

Study design

This is a multicentre, single blind, cross-over trial in which 24 patients will be included.
Upon inclusion, the treating physician will be asked what the patient*s SoC Hb-trigger is and what the standard amount of RBC products transfused to that specific patient is. This will then be called a SoC transfusion.
Patients will receive, in randomized order, 1. a SoC transfusion, 2. a SoC+1 RBC transfusion and 3. SoC+2 RBC transfusion. In the case that a SoC transfusion for a patient is >=3 units, SoC+2 will change into SoC-1 (one RBC unit less than SoC) to avoid cardiac overload and logistical issues due to too many units to transfuse. Between all study transfusions, a SoC transfusion will be given as a means of wash-out. This cross-over design in which patients are their own control reduces bias by adjudication order. Blood will be drawn <72hr before and <2hr after transfusion to measure Hb. Patients will complete a QoL-questionnaires (QUALMS and MFI) and a Rapid Visual Information Processing test (RVP) from the Cambridge Neuropsychological Test Automated Battery (CANTAB) 2 days before and 7 days after transfusion and again 2 days before the next transfusion. at the same timepoints, patients will measure their bloodpressure and pulse with a Withings BPM connect. They also will wear a Withings Steel HR smartwatch during the 3 red blood cell transfusion cycles. Patients will start wearing the smartwatch 7 days prior to a planned RBC transfusion to generate baseline data and continue to wear the device at least until the next transfusion. At the end of a transfusion cycle, the patient will fill out a short questionnaire on their experience of the last transfusion cycle. Both the questionnaires and completion of the cognitive tasks can be monitored remotely. Patients missing a measurement will be sent a reminder to make up for a missed task.

Intervention

1 or 2 extra RBCs added to a standard of care transfusion

Study burden and risks

15 questionnaires, 9 cognitive games and venapuncture of 3 x 3 ml spread over 2-6 months

Furthermore 3 times a period of 2-8 weeks of wearing the smartwatch(dependent of transfusion regime of patient)

Part 2: (optional) Qualitative interview (30-45 min) and focus group (45-60 min)

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

MDS or MPN with chronic red blood cell transfusion dependency

Exclusion criteria

Arrythmias

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-09-2021
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	22-12-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	28-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	29-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	25-08-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	01-11-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	27-01-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	19-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	22-04-2025
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23694
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL73847.058.20