Remote patient Monitoring in adults receiving red blood cell Transfusion for hematological disorders * a Pilot study of the physIQ Real World Monitoring platform using wearable biosensors

Published: 24-09-2019
Last updated: 10-04-2024

Primary objectives:- to explore transfusion induced differences in vital (activity) parameters such as heart rate, respiratory rate and activity before and after RBC transfusions in regularly transfused patients using the pinpointIQ* system.- To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Red blood cell disorders
Study type	Observational non invasive

Summary

ID

NL-OMON50160

Source
ToetsingOnline

Brief title
ReMoT

Condition

- Red blood cell disorders

Synonym
chronic anemia, myelodysplastic syndrome

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Research pot van de hematologieafdeling hagaziekenhuis

Intervention

Keyword: Biosensor, Continuous monitoring, Transfusion

Outcome measures

Primary outcome

- Processed data sets collected from continuous monitoring with the VitalPatch

including, but not limited to: heart rate; respiratory rate and activity.

- A significant difference in mean heartrate per day before and after

transfusion, large enough in comparison to the standard deviation of the mean

to power a study with a reasonable sample size (<150pt).

Secondary outcome

- Processed data sets collected from continuous monitoring with the Withings

steel HR including, but not limited to: heart rate; respiratory rate and

activity.

- PROMIS SF Questionnaire

- QUALMS Questionnaire

- CANTAB RVP Cognitive tool

- Amount of RBC units transfused

Study description

Background summary

Patients with haematological diseases receive more than half of the total volume of transfused red blood cells (RBCs) in The Netherlands. Apart from prediagnostics, storage and transportation, the total costs for RBCs for this group are about 60 million euros a year. In spite of these costs, there is a lack of evidence to support a specific or optimal transfusion strategy.
Adverse events of RBC transfusions, like transfusion reactions, iron overload and poor clinical outcomes in studies with a liberal transfusion thresholds are reasons for considering a restrictive transfusion strategy.
One parameter for determining transfusion timing could be the patient vital signs and activity. Measuring decrease in activity/detoriation in vital signs due to chronic anaemia and subsequent gain in activity/vital signs after RBC transfusions objectively through continuous vital parameter measurements, with a device like PhysIQTM*s VitalPatch®, is therefore of vital importance to be able to create evidence-based guidelines on when and how to transfuse as restrictively as possible without compromising quality of life(QoL).
Effectively determining this would mean a lower transfusion rate and a significant decrease in healthcare costs. Furthermore, we are interested to see whether transfusion and transfusion-induced changes in vital signs/activity change QoL and cognition, and whether data derived through the pinpointIQ* system could be used to indicate the need for transfusion. Lastly, we want to assess whether data captured by a Withings Steel Smartwatch is as usable as that captured by the VitalPatchTM, for possible improvement of wearability in the future.

Study objective

Primary objectives:
- to explore transfusion induced differences in vital (activity) parameters such as heart rate, respiratory rate and activity before and after RBC transfusions in regularly transfused patients using the pinpointIQ* system.
- To find a significant difference in mean heartrate per day before and after transfusion, large enough in comparison to the standard deviation of the mean to power a study with a reasonable sample size.

Secondary objectives:
- compare the transfusion induced effect on vital signs to the number of transfused units;
- assess correlations between biosensor data and patient-reported physical function collected via ePRO;
- in case of a transfusion reaction: capture vital signs during the transfusion reaction using the pinpointIQ* system;
- compare data collected by the VitalPatch® and the Withings Steel Smartwatch;

Study design

This is an observational single-arm open label pilot study in which 5 patients

will be enrolled.

Study burden and risks

Risks: Possible irritation of skin at placement site of VitalPatchTM or at the wrist.

Burden: Patients wear a VitalPatch® and a Smartwatch for 28 days and a second smartwatch for 7 days, fill out an eight-question PROMIS short form 14 times, complete a 33-item QUALMS-questionnaire 5 times and complete a 5 minute cognitive CANTAB tool 5 times.

Benefits: continuous monitoring which allows for a quick reaction to serious adverse events; possible improvement of QoL due to patients knowledge that they are being monitored; the VitalPatchTM will free up time for the clinician and nurse and provide flexibility when to see a patient, in case time-specific traditional measurement of vital signs (at the bedside) is no longer required.

Contacts

Public
HagaZiekenhuis

Els borst-eilersplein 275
Den Haag 2545 AA
NL
Scientific
HagaZiekenhuis

Els borst-eilersplein 275
Den Haag 2545 AA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

18 years old or above
in need of at least 1 red blood cell transfusion each month

Exclusion criteria

Cardiological conductivity disorder
Severe pulmonary comorbidities
Known skin allergies
Participating in another clinical study

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-12-2019
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	VitalPatch

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-09-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-11-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-05-2020
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

No registrations found.

In other registers

Register	ID
CCMO	NL70534.098.19