Mitochondrial Oxygen Tension Improves not upon Fluid Administration but after Transfusion of Erythrocytes (MOTIFATE) in chronic anemia patients (a pilot study)

Published: 11-02-2016 Last updated: 19-04-2024

The study will compare the change in cutaneous cellular oxygen availability, measured as mitochondrial PO2 (mitoPO2) between a fluid challenge and a blood transfusion in chronic anemia patients.

Ethical review Approved WMO

Status Recruitment stopped

Health condition type Anaemias nonhaemolytic and marrow depression

Study type Observational invasive

Summary

ID

NL-OMON43442

Source

ToetsingOnline

Brief title

MOTIFATE-pilot study

Condition

Anaemias nonhaemolytic and marrow depression

Synonym

Chronicle anaemia, low Hb level

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anaemia, Oxygen

Outcome measures

Primary outcome

The primary endpoint of the study is cellular oxygen availability in skin (mitoPO2 in mmHg) and its differential response to RBC transfusion compared to fluid challenge.

Secondary outcome

- * Determine the cutaneous oxygen availability in relation to Hb level before and after a fluid challenge of 500 ml of normal saline.
- * Determine the cutaneous oxygen availability in relation to Hb level before and after a blood transfusion.
- * Determine the change in cutaneous oxygen availability by a fluid challenge of 500 ml of normal saline.
- * Determine the change in cutaneous oxygen availability by a blood transfusion.
- * Explore the clinical usability of the COMET monitor in blood transfusion treatments.

Study description

Background summary

To date no appropriate measurement technique exists to determine when the

2 - Mitochondrial Oxygen Tension Improves not upon Fluid Administration but after Tr ... 24-05-2025

benefits of a red blood cell transfusion outweigh the transfusion related risks on an individual level. The preclinical finding that anemia-induced low Mitochondrial Oxygen Tension Improves not upon Fluid Administration but after Transfusion of Erythrocytes (MOTIFATE) is a key principle in our quest for a novel transfusion trigger. Demonstrating that the MOTIFATE principle also accounts to humans is a necessary first step in further clinical evaluation of the use of mitochondrial oxygen tension (mitoPO2) in personalized transfusion medicine. In this pilot study we want to research the MOTIFATE principle in a low-risk patient population consisting of hematological chronic anemia patients.

Study objective

The study will compare the change in cutaneous cellular oxygen availability, measured as mitochondrial PO2 (mitoPO2) between a fluid challenge and a blood transfusion in chronic anemia patients.

Study design

Single centre non-blinded randomized controlled trial.

Study burden and risks

The intracellular oxygen measurement is a non-invasive measurement technique and does not lead to deviations from standard protocols. The specific discomfort for the patient is that an aminolevulic acid containing-plaster is applied which makes the skin sensitive for light. This plaster is applied at least 4 hours before a measurement can be done. The measurement device is called the COMET monitor, able to measure cutaneous mitoPO2 and mitochondrial oxygen consumption (mitoVO2) by means of oxygen-dependent quenching of delayed fluorescence of mitochondrial protoporphyrin IX. The additional fluid challenge of 500 ml pre-warmed saline should be very well tolerable for adult patients without heart or kidney failure. Overall, the study comes with a negligible risk and the burden is very low.

Contacts

Public

Selecteer

Wytemaweg 80 Rotterdam 3015CN NL

Scientific

Selecteer

Wytemaweg 80 Rotterdam 3015CN NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- * Be scheduled to receive a blood transfusion
- * Has a Hb level below the value indicated for red blood cell transfusion according to current transfusion guidelines for chronic anemia or
- * Has a Hb level above the value indicated for red blood cell transfusion according to current transfusion guidelines but presents with clinical symptoms of (too) low Hb (e.g. fatigue and general malaise).

Exclusion criteria

- * Age < 18 years
- * History or signs of heart failure
- * Kidney failure with fluid restriction
- * Porphyria
- * Hemoglobinopathy
- o Hemoglobin C disease
- o Hemoglobin S-C disease
- o Thalassemia
- o Sickle cell anemia

Study design

Design

Study type: Observational invasive

Intervention model: Parallel

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 21-03-2016

Enrollment: 32

Type: Actual

Ethics review

Approved WMO

Date: 11-02-2016

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Approved WMO

Date: 09-06-2016

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

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 NL55664.078.15

Study results

Date completed: 28-02-2017

Results posted: 29-08-2017

Actual enrolment: 32

First publication

29-08-2017