# 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
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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.

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|---|---|
| **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

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
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NL
**Scientific**

Selecteer

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# 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

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 21-03-2016 |
| Enrollment: | 32 |
| Type: | Actual |

# Ethics review

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|---|---|
| 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

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|---|---|
| Date completed: | 28-02-2017 |
| Results posted: | 29-08-2017 |
| Actual enrolment: | 32 |

**First publication**
29-08-2017