Protocol C: Microcirculatory response to phlebotomy in adult patients with Eisenmenger syndrome.

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Aim of the proposed study will be to investigate whether microvascular blood flow at baseline is impaired in Eisenmenger patients who experience symptoms of the *hyperviscosity syndrome*. Furthermore, in view of the controversy whether to perform…

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

Summary

ID

NL-OMON31046

Source
ToetsingOnline

Brief title
CARMICI - protocol C.

Condition

- Red blood cell disorders
- Congenital cardiac disorders

Synonym
Eisenmenger syndrome, phlebotomy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Eisenmenger syndrome, Microcirculation, Sidestream Dark Field imaging, Sublingual

Outcome measures

Primary outcome

Microvascular flow index (MFI), obtained by semi-quantitative analysis of the

SDF video sequences.

Secondary outcome

Not applicable.

Study description

Background summary

Eisenmenger syndrome is a congenital anomaly of the heart. In this syndrome, an initial left-to-right central shunt subsequently reverses due to the development of pulmonary hypertension. The hypoxaemia resulting from a right-to-left shunt is compensated by an increase in haemoglobin concentration (Ned Tijdschr Geneeskd 1999;143(10):501-5). Most patients have a compensated erythropoiesis with stable haemoglobin that requires no intervention. However, polycythaemia can lead to symptoms associated with hyperviscosity of the blood, like headache and gout. These symptoms may be relieved by removal of one unit of blood (phlebotomy), always with an equal volume replacement. This treatment is recommended in patients with haematocrit >0.65 with signs of hyperviscosity (Eur Heart J 2003;24;1035-1084). However, therapeutic phlebotomy in cyanotic heart disease is controversial. Data suggest that phlebotomy has the potential to increase exercise capacity, reduce the symptoms of hyperviscosity, and reduce the potential risk of vaso-occlusive disease in selected patients. However, removing blood may stimulate the bone marrow to produce even more red cells. Furthermore, repeated phlebotomy depletes the iron stores and may result in the production of iron-deficient red cells. These microcytic erythrocytes are less deformable than normocytic erythrocytes and increase the risk of stroke by increasing blood viscosity (Cardiol Rev 2007;15(1):31-4).
Recently, a two-dimensional imaging technique (called sidestream dark-field (SDF) imaging) was developed and validated to assess microcirculatory blood flow.

Study objective

Aim of the proposed study will be to investigate whether microvascular blood flow at baseline is impaired in Eisenmenger patients who experience symptoms of the *hyperviscosity syndrome*. Furthermore, in view of the controversy whether to perform phlebotomy or not, the effect of phlebotomy and successive volume replacement on the microcirculation will be studied.

Study design

Observational study.
The imaging technique has been described in detail in protocol A, which already was approved by the medical ethical committee of Erasmus MC (MEC-2006-352).
Sublingual SDF imaging will be performed three times:
1. Before phlebotomy (T0 = baseline).
2. Ten minutes after removal of 500 ml of blood (T1).
3. Ten minutes after 500 cc saline replacement. (T2).

Together with SDF imaging, the following data will be collected:
Length, weight, cardiac risk profile (diabetes mellitus, hypertension, dyslipidemia, smoking), current medication use, body temperature, heart rate and rhythm, arterial blood pressure, haemoglobin, haematocrit.

Hemoglobin concentration and hematocrit will be measured in routinely taken blood samples.

Study burden and risks

Not applicable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Eisenmenger syndrome patients with inclusion criteria:
1. Age of 18 years or older
2. Indication for therapeutic phlebotomy, i.e. haematocrit >0.65 and signs of hyperviscosity.

Exclusion criteria

1. Pregnancy.
2. Oral bleeding.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	01-01-2008
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2007
Application type:	First submission
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	NL19055.078.07