Assessing fetal hemoglobin in patients on Tranylcypromine

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Ethical review	Approved WMO
Status	Pending
Health condition type	Haemoglobinopathies
Study type	Observational invasive

Summary

ID

NL-OMON41063

Source
ToetsingOnline

Brief title
TCP-HbF

Condition

- Haemoglobinopathies

Synonym
Hereditary anemia, sickle cell disease

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: Fetal hemoglobin, Monoamine oxidase inhibitor, Sickle cell disease, Tranylcypromine

Outcome measures

Primary outcome

The amount of HbF in peripheral blood. In adults the amount of HbF is normally less than 1% of the total amount of hemoglobin. HbF levels should be increased to at least 3% in order to use the results of this study for the design of a follow-up study investigating the effect of Tranylcypromine on HbF levels in sickle cell disease patients.

Secondary outcome

Not applicable.

Study description

Background summary

World-wide, the anemias are the most common hereditary disorders. The patients have problems with hemoglobin, the most important protein in red blood cells. The most common form of hereditary anemia is sickle cell disease. It is estimated that there are around 600 patients with sickle cell disease in the Rotterdam area alone. Before birth, humans express a special "baby" hemoglobin called fetal hemoglobin (HbF). If the patients could replace their pathologic adult sickle hemoglobin (HbS) by fully functional HbF, their conditon would vastly improve. Currently, there are no pharmacological compounds known that can efficiently reverse the switch from HbS to HbF. Recent research indicates that Tranylcypromine may possess these properties. Some psychiatric patients already take Tranylcypromine as part of their regular treatment. In this study we wish to determine if these patients have increased HbF levels in their peripheral blood. If we find that this is indeed the case, we will investigate next whether Tranylcypromine could be given to sickle cell patients to increase HbF levels. These follow-up investigations are not part of the current study.

Study objective

The objective of ths study is to investigate whether use of Tranylcypromine, a monoamine oxidase inhibitor, results in increased expression of HbF in adults. If this is the case, we will use the results of this study to design follow-up research investigating whether use of Tranylcypromine also results in increased HbF levels in sickle cell disease patients.

Study design

From the subjects (n=10), a maximum of 10 ml of peripheral blood will be collected through venipuncture, for a maximum of 2 times. This will be used to determine the amount of HbF, both at the protein and the mRNA level. Left-over material will be stored frozen so the analysis can be repeated when needed, without the requirement for collecting a fresh blood sample.

Study burden and risks

Burden: donation of a maximum of 2 blood samples with a maximum volume of 10 ml each, through venipuncture. Risk: nausea and/or fainting in case of hemophobia. Patients with known hemophobia are excluded from participating in this study.

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

Adult patients who give consent, taking Tranylcypromine for 2 months or longer, prescribed by their attending physician as part of their regular treatment.

Exclusion criteria

Non-compliance; hemophobia.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-07-2014

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	NL47963.078.14