Obtaining blood from healthy volunteers for assay validation on iron parameters.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON46555

Source
ToetsingOnline

Brief title
HAVIP

Condition

- Other condition

Synonym
Iron disorders

Health condition

Iron disorders

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Assay, Iron parameters, Validation

Outcome measures

Primary outcome

The main study endpoint for this study is storage of blood from healthy

volunteers to use in the validation of an ERFE assay.

Secondary outcome

The use of the stored plasma and serum for the validation of assays in the

field of iron metabolism in the next 10 years.

Study description

Background summary

The research of the Radboudumc Expertise Center for Iron disorders focuses on the understanding of the iron metabolism, in particular the identification and characterization of novel factors that affect dysregulation of iron homeostasis in various human disorders among which are some of the world's most prevalent diseases such as iron deficiency, anemia of chronic (kidney) disease, hereditary hemochromatosis, inherited (iron loading) anemias, and malarial infections. New findings are translated into novel diagnostic assays and therapeutic strategies that can be implemented in the clinic.

Study objective

New assays need to be validated before they can be implemented in research or in the clinic. The validation of assays consists of several steps. First a proof of principle must be performed to determine whether the assay is capable of measuring the specific protein the assays is targeted at. It indicates whether the assay is biologically plausible. Samples used usually consist of patient samples and samples from healthy volunteers. The assay is biologically

plausible when a difference in outcome in patient samples and samples from healthy volunteers can be measured.
Secondly, the assay has to be analytically validated. This is done by measuring several analytical characteristics of the assay e.g linearity, accuracy and precision.
Lastly a biological validation of the assay has to be performed. This test determines the biological plausibility of the assay and (often) shows the correlation between the protein of interest and other parameters. Patient samples and samples from healthy volunteers are often used for these test.

As described above, samples from healthy volunteers are needed in several steps of the validation process of an assay. The material of healthy volunteers can also be used to get a first impression of reference values (of what is considered healthy). These references values are important in daily practice since they can serve as a diagnostic tool. The importance of samples from healthy volunteers is therefore undeniable during these type of studies.

Study design

The study is an observational study with invasive measurements. The invasive measurement in this study is the obtaining of blood from healthy volunteers. The blood withdrawal will be performed according to standard procedures of the radboudumc hospital. The processing and storage of the blood will be performed according to the protocol of the radboud biobank. This protocol is attached under the name C1.protocolbijlageSOPbiobank.1.03042018

Study burden and risks

The risk of blood drawing is low, but there is a chance of unsolicited findings. The parameters that are tested are parameters concerning the iron metabolism e.g. EPO, hepcidin, soluble transferrin receptor and ERFE. Deviating results could be found during these tests. Volunteers will be informed when unsolicited findings are made.

The benefit of these studies are validated diagnostic tests and a first impression of reference values.

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

Participants need to be healthy volunteers between 18 and 55 years old. They should live in the Netherlands and preferably in the area of Nijmegen. People who are diagnosed with any iron disorder can not participate in this study. Examples of Iron disorders are anemia, β-thalassaemia, hemochromatosis and IRIDA. Also people that use any sort of medication can not participate, however the use of contraceptive pills is allowed.

Exclusion criteria

If deviant iron parameter values are found in samples of the healthy volunteers they will be excluded from the study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	17-05-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL65219.091.18