Towards harmonization of hepcidin assays worldwide: identification of a commutable reference material for international use

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Iron and trace metal metabolism disorders
Study type	Observational invasive

Summary

ID

NL-OMON43068

Source
ToetsingOnline

Brief title
Hepcidin harmonization study

Condition

- Iron and trace metal metabolism disorders

Synonym
iron overload, Ironmetabolismdisorder

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,BV van de researchgroep

Intervention

Keyword: Harmonization, Hepcidin, Reference material

Outcome measures

Primary outcome

The primary study parameters are:

1. Commutability of the secondary reference material;

2. An inter-assay CV of <10% obtained with a mathematical simulated

harmonization - with results of the reference material measured by assays with

an intra-assay CV of < 8.0%;

3. Stability of the reference material for 5 years;

4. Production of ~2600 vials of 350 µl reference material for long term

international use on a "fee for service basis".

Secondary outcome

Not applicable.

Study description

Background summary

Serum hepcidin holds great promise as target of therapy and biomarker for diagnosis and monitoring of iron disorders. Currently, large differences are found in absolute hepcidin levels measured by different assays. To facilitate use of hepcidin in clinical practice and research, equivalence between hepcidin assays needs to be improved, which can be achieved by harmonization (i.e.when results are equivalent by being traceable to a secondary reference material).

By developing an international, commutable* (secondary) calibrator for different hepcidin assays, this study will contribute to harmonization. This

will facilitate: i) determination and application of general accepted reference intervals and clinical decision-limits and ii) comparison and pooling of data obtained from different studies. This will improve research and clinical translation in this field.

A previous harmonization study investigated different types of reference materials. Lyophilized, native (heparin) plasma with cryolyoprotectant CLP5 (increases stability) showed to be commutable and therefore suitable as international calibrator for hepcidin assays. Our hypothesis is that lyophilized, native serum with CLP5 will also be commutable and therefore suitable as international secondary reference material for harmonization of hepcidin assays worldwide.

* Commutable means that the reference material and native patient samples will behave similar in different assays.

Study objective

The current study is designed to validate the secondary reference material identified in the previous study, and to produce a larger batch of this new calibrator for harmonization of worldwide hepcidin assays the next 5 years. For that reason, our objective is:
* Will lyophilized native serum with CLP5 also be suitable as international secondary reference material for harmonization of worldwide hepcidin assays to obtain equivalent results for clinical samples regardless of the assay used.
And if so;
* Is it possible to produce enough secondary reference material for harmonization of hepcidin assays worldwide, that will be stable for the next 5 years.

Study design

Biomarker assay harmonization study; an international send-out of human serum for an one-time measurement with 11 different assays at 10 different laboratory.

Study burden and risks

Hemochromatosis patients are treated with phlebotomies. For this study, we aim to use this blood (which otherwise will be destroyed). These patients will not be subjected to extra interventions than their regular treatment.

Volunteers will be subjected to a venipuncture twice. Depending on their serum hepcidin and ferritin concentrations which will be determined through a pre-screening (bloodcollection of 3 ml), either 300 ml or 50 ml blood will be collected during the second puncture. The risks concerning this venipuncture

will be minimal.

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

All phlebotomy patients that we can include within 2 weeks and healthy volunteers. Both age between 20-65 years. They should not be HIV, hepatitis B or hepatitis C positive.

Exclusion criteria

To prevent induction of hypoferremia (shortage of iron), no blood will be collected for the second time for volunteers with a ferritin concentration of < 40 µg/L, and max. 50 ml blood

will be collected for volunteers with a ferritin concentration between 40 - 70 µg/L.
The blood of all subjects will be tested for HIV, hepatitis B and hepatitis C. A subject will be excluded if they appear to be positive for one of these three.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2016
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	29-04-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-06-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-07-2016
Application type:	Amendment
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	NL56910.091.16