

Whole blood donation by healthy volunteers

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To obtain whole blood from healthy volunteers for the purpose of preparing calibration, quality control or other samples for analytical methods (e.g. HPLC and LC-MS/MS).

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

Summary

ID

NL-OMON45457

Source

ToetsingOnline

Brief title

Blood donation

Condition

- Other condition

Synonym

Blood taking, drawing blood

Health condition

Not applicable

Research involving

Human

Sponsors and support

Primary sponsor: QPS Netherlands B.V.

Source(s) of monetary or material Support: QPS Netherlands

Intervention

Keyword: Blood, Donation, Healthy, Whole

Outcome measures

Primary outcome

N.A.

Secondary outcome

N.A.

Study description

Background summary

See section C4.

Study objective

To obtain whole blood from healthy volunteers for the purpose of preparing calibration, quality control or other samples for analytical methods (e.g. HPLC and LC-MS/MS).

Study design

Healthy male or female subjects will be recruited to donate blood (with a maximum of 500 mL every 10 weeks), with a maximum of 5 (men) and 3 (women) times a year. The blood donation procedure will be performed at QPS Netherlands B.V.

Study burden and risks

The blood collection procedure is not dangerous, but may cause discomfort or bruising. Occasionally, fainting, bleeding or an infection at the blood sampling site can occur.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Provision of written informed consent.

Male and female 18 * 65 years of age, inclusive.

Healthy according to the normal procedures according to medical history, physical examination, laboratory values (Hb content) and vital signs, unless the investigator considers an abnormality to be clinically irrelevant.

Minimal weight of 50kg

Exclusion criteria

A history of, or presence of diseases or other conditions in which no blood donation can take place (as judged by the investigator).

Blood donation in the previous two months.

Evidence of having hepatitis or being HIV positive.

Current abuse of alcohol or drugs.

Pregnancy.
Positive drug screen, according to QPS work instructions.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 25-08-2017

Enrollment: 50

Type: Anticipated

Ethics review

Approved WMO

Date: 03-01-2018

Application type: First submission

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL60791.056.17