An open-label study to determine the usefulness of the dried blood spot method for phenotyping and genotyping of CYP450 enzymes and the determination of trace elements in healthy volunteers.

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The objective of this research is to compare the results of the analysis of midazolam between the dried blood spot method, plasma and whole blood.

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

Summary

ID

NL-OMON35088

Source
ToetsingOnline

Brief title
Protocol 093893-CS0145: dried blood spot

Condition

- Other condition

Synonym
Not applicable

Health condition

Niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: Xendo Drug Development
Source(s) of monetary or material Support: Xendo Drug Development BV

Intervention

Keyword: Dried blood spot, Genotyping, Healthy volunteers, Phenotyping

Outcome measures

Primary outcome

To compare the results of analysis of midazolam between the dried blood spot method and plasma as well as whole blood, all drawn by venipuncture.

Secondary outcome

- To compare the results of dried blood spot analysis of midazolam between blood drawn by finger prick and venous whole blood.

- To compare the results of dried blood spot analysis of midazolam between using 1 and using 2 dots of the dried blood spot analysis card.

- To compare the results of dried blood spot analysis of midazolam between using a 3mm and a 6 mm punch from the dried blood spot analysis card.

- To evaluate the effect of storage time on the dried blood spot analysis of midazolam.

- To compare genotyping of CYP3A4, CYP3A5, CYP2D6 and CYP2C19 between dried blood spots and whole blood samples.

- To compare AUC of midazolam between the use of limited sampling and extensive sampling.

- To investigate the feasibility of measuring 1-OH midazolam by dried blood

spot analysis.

- To investigate the feasibility of measuring trace elements by ICPMS from

dried blood spots (exploratory).

- To evaluate subject-, nurse-, and technician satisfaction of dried blood spot

method versus venous blood sampling using a standardized questionnaire

(exploratory).

Study description

Background summary

With this study Xendo will determine the usefulness of the so-called dried blood spot method for taking blood samples and processing of blood samples for analysis of midazolam, for for phenotyping and genotyping liver enzymes and the determination of trace elements.

Study objective

The objective of this research is to compare the results of the analysis of midazolam between the dried blood spot method, plasma and whole blood.

Study design

This study is an open-label study in 12 healthy subjects. After assessing eligibility the subjects will come to the clinic1 h pre-dose. The subjects will receive a single dose of midazolam of 7,5 mg. During this day bloodsamples will be taken until 12h post dose by a venous canula or finger prick.

Intervention

The study will start with a screening. At the screening the weight will be measured, a blood and urine sample will be taken for laboratory tests and an alcohol breath test and drug screen will be done.
During the stay in the clinic the subject will receive 7.5 mg midazolam. Furthermore blood will be taken frequently and an alcohol breath test and drug screen will be done. Two questionairres will be filled in as well.

Study burden and risks

The drug midazolam is well tolerated in general. There were some adverse events reported in relation with the drug. These were dizziness, headache and drowsiness. The expectation is that the drowsiness is ended when the subjects leave the clinic, if not the subject will stay for one night in the clinic.
Based on many years of experience from midazolam as a drug the current dose is chosen. The risks with these doses is likely to be minimal, but as with all clinical drug studies, unforeseeable adverse reactions could occur.

Blood sampling is not dangerous, but can be sensitive or cause bruising.
Rarely, fainting or a local inflammation occurs at the place of sampling.

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

Healthy male and female
Age between 18-45 years

Exclusion criteria

Clinical significant abnormalities at medical research

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2010
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	25-03-2010
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	NL31394.056.10