A screening protocol to collect a blood sample for the pharmacogenetic profiling of metabolic enzymes and drug transporters in male and female volunteers.

Published: 28-10-2019
Last updated: 10-04-2024

Determination of the individual genotypes for drug metabolizing enzymes and transporters among volunteers, in order to design dedicated clinical trials in a subpopulation, for (potential new) drugs that are substrates, inducers or inhibitors of...

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

Summary

ID

NL-OMON49124

Source
ToetsingOnline

Brief title
CS0327 - Genotyping

Condition

- Other condition

Synonym
genetic pharmacological research, pharmacogenetics

Health condition

pharmacogenetics

Research involving
Human

Sponsors and support

Primary sponsor: QPS Netherlands B.V.
Source(s) of monetary or material Support: QPS Netherlands B.V.

Intervention

Keyword: Drug metabolic enzymes, Drug transporters, Genotyping

Outcome measures

Primary outcome

Distribution of genotype of p-Gp, BCRP, OATP1B1, OATP1B, OAT1, OAT3, OCT1,

OCT2, MATE1, 5-HTTLPR, CYP1A2, CYP2D6, CYP2C9, CYP2C19, CYP3A4.

Secondary outcome

N.ap.

Study description

Background summary

This study entails the collection of a blood sample of volunteers for genotyping metabolic enzymes and drug transporters, in order to have insight in the distribution of the various genotypes for drug metabolizing enzymes and transporters among the volunteer*s pool of QPS.
Within drug development it is increasingly recognized by regulatory bodies that one of the reasons for the inter-subject variation in the pharmacokinetics of a (potential new) drug is the genotype of metabolizing enzymes or drug transporters.

Study objective

Determination of the individual genotypes for drug metabolizing enzymes and transporters among volunteers, in order to design dedicated clinical trials in a subpopulation, for (potential new) drugs that are substrates, inducers or inhibitors of particular metabolic enzymes or transporters.

Study design

A prospective, observational cohort study.

Study burden and risks

The burden for participants is a single blood sample of 20 mL. No additional venepuncture is needed, this sampling only concerns additional tubes.

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

1. Provision of written informed consent.

2. Male and female subjects aged >=18 years.

Exclusion criteria

1. Previous participation in the current screening protocol.
2. The subject is, in the opinion of the Investigator, unlikely to comply with the protocol or considered unsuitable for this study. For instance, when drawing 20 mL of blood is exclusionary for a planned participation in a QPS clinical trial.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2019
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	28-10-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-02-2020

Application type:	Amendment
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	NL71021.056.19