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Study to look at the variability of tests of blood vessel function in several different groups of people

Submission date	Recruitment status	[_] Prospectively registered
14/02/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/03/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/04/2024	Circulatory System	

Plain English summary of protocol

Background and study aims
There are a lot of studies investigating medication that can potentially affect the characteristics of human blood vessels and how they work. To be able to properly explore these effects, reliable, safe and non-invasive tests are needed. This study aims to develop these tests, measuring how much they vary over time and between different people. In the study, different types of cameras and microscopes will be used to look at blood flow in the skin, oxygen content in the skin, the function of skin cells, function of blood vessels and characteristics of small blood vessels. These tests are further explained in the participant information sheet.

Who can participate?
Healthy adult volunteers aged 18 - 30 years.

What does the study involve?
The study consists of two visits, in which all tests described above are done once per participant. All of the tests are non-painful. Total duration of each visit is approximately 2 hours.

What are the possible benefits and risks of participating?
There are no direct benefits of participation in the study, but the data collected will help to improve research in the field. There are no risks associated with participation.

Where is the study run from?
Centre for Human Drug Research (the Netherlands)

When is the study starting and how long is it expected to run for?
December 2021 to February 2022

Who is funding the study?
Centre for Human Drug Research (the Netherlands)

Who is the main contact?
Dr Matthijs Moerland, mmoerland@chdr.nl

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CHDR2156

Study information

Scientific Title
Observational study to evaluate inter-and intra-subject variability of microcirculatory and endothelial functional tests and differences in these tests between several subject populations

Study objectives
Functional tests of endothelial function and microcirculation can be used to evaluate clinical effects in clinical trials.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics approval required (non-WMO research)

Study design
Observational single-centre longitudinal cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Endothelial function and microcirculatory function

Interventions
Eight healthy volunteers will be assessed in this study on two separate study days. The Screening Visit will be conducted at day 1. Each study day subjects will undergo a battery of endothelial testing, which consists of the following measurements: Flow Mediated Skin Fluorescence (FMSF), laser speckle contrast imaging (LSCI), near infrared spectroscopy (NIRS), side-stream dark field microscopy (SDFM) and passive leg movement (PLM), in no particular order. However, LSCI_LTH measurements will be performed after LSCI_PORH.

Intervention Type
Other

Primary outcome(s)
Endothelial function and microcirculation measured with FMSF, LSCI, NIRS, SDFM and PLM on two study days

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
20/02/2022

Eligibility

Key inclusion criteria
1. Male and females, 18 to 30 years of age, inclusive.
2. Subject has voluntarily signed informed consent form.
3. Willingness and ability to comply with all study procedures
4. Body mass index (BMI) between 18 and 30 kg/m²

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Evidence of any active or chronic disease or condition that could interfere with the conduct of the study (following a detailed medical history, physical examination, vital signs (systolic and diastolic blood pressure, pulse rate, body temperature).
2. Receival of any study drug within 30 days or 5 times ½ half-life, whichever greater prior to day 1.
3. Participation in an investigational drug or device study (last dosing of previous study was within 90 days prior to first dosing of this study).
4. History of abuse of addictive substances (alcohol, illegal substances) or current use of more than 21 units alcohol per week, drug abuse, or regular user of sedatives, hypnotics, tranquillisers, or any other addictive agent.
5. Alcohol intake 24h prior to the study day.
6. Is demonstrating excess in caffeine consumption (more than eight cups of coffee or equivalent per day.
7. If a woman, pregnant, or breast-feeding, or planning to become pregnant during the study
8. Any daily nicotine use or regular use of nicotine products.
9. Positive nasopharyngeal rapid antigen test for SARS-CoV-2 at admission to the clinical research center
10. Subject has received any vaccination in the last 2 weeks prior to Visit 1

Date of first enrolment
01/01/2022

Date of final enrolment
12/02/2022

Locations

Countries of recruitment
Netherlands

Study participating centre
Centre for Human Drug Research
Zernikedreef 8
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Sponsor information

Organisation
Centre for Human Drug Research

ROR
https://ror.org/044hshx49

Funder(s)

Funder type
Research organisation

Funder Name
Centre for Human Drug Research

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from CHDR project leader or principal investigator. (clintrials@chdr.nl)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/05/2023	04/04/2024	Yes	No
Participant information sheet	version 1	08/12/2021	18/02/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1	08/12/2021	18/02/2022	No	No