Symptom Picture of Homeopathic Medicine *X in Healthy Volunteers: a randomised, double-blind, placebo-controlled study

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To record all reactions of healthy volunteers induced by the use of a homeopathic medicine and placebo.

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

Summary

ID

NL-OMON40893

Source
ToetsingOnline

Brief title
Homeopathic Drug Proving

Condition

- Other condition

Synonym
not applicable

Health condition

nvt betreft homeopathische geneesmiddelproef bij gezonde vrijwilligers

Research involving
Human

Sponsors and support

Primary sponsor: SANUM-Kehlbeck GmbH & Co. KG
Source(s) of monetary or material Support: bedrijven

Intervention

Keyword: Healthy volunteers, Homeopathic Drug Proving

Outcome measures

Primary outcome

Proving symptoms experienced by the volunteers and attributable to the

administration of the homeopathic medicine or placebo. For each symptom its

properties are recorded according to a predefined scheme.

Secondary outcome

not applicable

Study description

Background summary

Homeopathy is a medical system, founded by Samuel Hahnemann in 1796. The three main principles of this system are a) testing the effects of medicines on healthy volunteers (proving), b) the law of similars, and c) the use of potentised medicines. The *law of similars* states, that a homeopathic medicine, capable of provoking symptoms in a healthy person (a proving), acts as curative agent in a diseased person in which similar symptoms are manifested. Homeopathic Drug Provings (HDP) are thus necessary to provide information to prescribe the medicine for patients according to the law of similars, as well as for market authorisation of homeopathic medicinal products.

Study objective

To record all reactions of healthy volunteers induced by the use of a homeopathic medicine and placebo.

Study design

Randomised, double-blind, placebo-controlled study

Intervention

Homeopathic Medicine Aspergillus ruber C12 for oral administration versus placebo

Study burden and risks

The investigational product can cause reactions in participants, however they will be mild of nature and of a short duration. No serious adverse events have been reported. The investigational product as studied in the present study is in a dilution beyond Avogadro*s number. The study-related investment for participants is estimated to be maximum 47 hours over a period of 4 months. The most intensive period is in the first two weeks after start of the study. Travelling burden for the participants will be minimized to two or three times during the course of the study since contact by phone is planned as much as possible and supervisors are also willing to travel. Based on the time investment described above and the extremely low risk for the occurence of possible serious side effects, the advantages of contributing to the further development and availability of homeopathic medicinal products do outweight the study burden and possible risks.

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

•Between 18 years and 75 years old.
•Written informed consent
•Able to understand and read the Dutch language
•Accessible by telephone or internet

Exclusion criteria

•Subjects with serious mental-emotional disorders such as psychosis, major depression, anxiety disorder, bipolar disorder or similar.
•Planned medical/dental treatment during the HDP, including herbal or dietary supplements, procedures or medications that might interfere with, or substantially alter responsiveness of the participants to the homeopathic medicine proved. The use of contraceptive medication or intra-uterine devices is not an exclusion criterion.
•Pregnancy or lactation, or anticipating pregnancy during the course of the HPD.
•A known history of drug, alcohol and/or medication dependence or addiction
•Participation in another trial at the same time or within the last 3 months prior to the study.
•Current homeopathic treatment, or homeopathic treatment within 30 days prior to the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2014
Enrollment:	14
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Aspergillus ruber
Generic name:	Aspergillus ruber C12

Ethics review

Approved WMO Date:	29-04-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	10-06-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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
EudraCT	EUCTR2014-001239-35-NL
CCMO	NL48326.028.14