A double-blind, randomized study to evaluate plasma prolactin levels in healthy volunteers after single oral doses of lorazepam

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Evaluation of the effect of single oral doses of lorazepam on plasma concentration of prolactin

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Interventional

Summary

ID

NL-OMON37691

Source
ToetsingOnline

Brief title
Prolactin levels after single oral doses of lorazepam

Condition

- Hypothalamus and pituitary gland disorders
- Sleep disturbances (incl subtypes)

Synonym
hyperprolactinemia, increased prolactin levels

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research

Source(s) of monetary or material Support: Centre for Human Drug Research

Intervention

Keyword: healthy volunteer, lorazepam, prolactin

Outcome measures

Primary outcome

Plasma prolactin concentration

Secondary outcome

not applicable

Study description

Background summary

A stimulating effect of lorazepam and other GABA agonists on plasma prolactin levels are known from animal studies. In healthy volunteers, this effect has not been confirme. However, these studies suffered from small sample sizes. The present study aims to evaluate prolactin levels after administration of lorazepam or placebo in a larger population of healthy volunteers.

Study objective

Evaluation of the effect of single oral doses of lorazepam on plasma concentration of prolactin

Study design

Dubbel-blind, randomized and placebo-controlled, cross-over study with bloodsamples of healthy volunteers (n = 32) obtained in two other studies, in which the volunteers were administered single oral doses of 2 mg lorazepam or placebo.

These two studies are:
ClinicalTrials.gov identifier NCT00720421; EudraCT 2008-001756-51
ClinicalTrials.gov identifier NCT00720421; EudraCT 2008-001757-17

Intervention

not applicable

Study burden and risks

not applicable

Contacts

Public
Centre for Human Drug Research

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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

Not applicable. This study will consist of performing additional analysis of prolactin concentration in blood samples obtained from healthy volunteers in two other (separate) studies. Signed informed consent forms from all volunteers are available and cover this additional analysis. As a result, no new volunteers will be included

Exclusion criteria

Not applicable. This study will consist of performing additional analysis of prolactin concentration in blood samples obtained from healthy volunteers in two other (separate) studies. Signed informed consent forms from all volunteers are available and cover this additional analysis. As a result, no new volunteers will be included

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-06-2012
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	11-06-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL40111.058.12