EFFECTS OF RANDOMIZED, DOUBLE-BLIND, MULTIPLE DOSE ADMINISTRATION OF OLANZAPINE OR TOPIRAMATE PLUS OLANZAPINE ON THYROID FUNCTION, GLUCOSE AND LIPID METABOLISM IN HEALTHY MALES

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The objective of the study is to observe the effect of olanzapineat a dose of 10 mg daily for 14 days when given with/without topiramaat at a dose of 25 and 50 mg twice daily on bodyweight in healthy male subjects. In addition the effect of...

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

Summary

ID

NL-OMON34067

Source
ToetsingOnline

Brief title
olanzapine vs olanazapine/topiramate study

Condition

- Other condition
- Thyroid gland disorders

Synonym
body weight, thyroid function

Health condition

lichaamsgewicht

Research involving
Human

Sponsors and support

Primary sponsor: Project Management
Source(s) of monetary or material Support: PRA International

Intervention

Keyword: Body weight, Olanzapine, Topiramate

Outcome measures

Primary outcome

To compare the effects of 14 days of daily dosing of 10 mg olanzapine with or without topiramate at a dose of 25 and 50 mg twice daily on body weight in healthy male subjects

Secondary outcome

To assess if olanzapine at a dose of 10 mg daily for 14 days with or without topiramate at a dose of 25 and 50 mg twice daily has an effect on thyroid function, glucose and lipid metabolism in healthy male subjects

Study description

Background summary

Effect of olanzapine with or without topiramaat on the metabolism

Study objective

The objective of the study is to observe the effect of olanzapineat a dose of 10 mg daily for 14 days when given with/without topiramaat at a dose of 25

and 50 mg twice daily on bodyweight in healthy male subjects. In addition the effect of olanzapine on the thyroid gland and the metabolism of glucose and fat in the body will be observed.

Study design

Procedures and assessments:

Screening and follow-up:
Clinical laboratory, bloodpressure and vital signs, physical examination, 12-lead ECG, drug screen
Only by screening:
medical history, height, weight, HBsAG, anti HCV and anti-HIV.

subjects will be in the clinic for 2 periods. For Period 1, the subjects will arrive at the clinic 2 days preceding the day of the first drug administration (Day 1 is the day of (the first) drug administration) and they will leave on Day 16 (48 hours after the last drug administration). For Period 2, the subjects will arrive at the clinic on Day 27 and they will leave the clinic on Day 28.

Intervention

Active substance :olanzapine topiramate
Activity : anti-psychotic anti-epileptic
Indication : schizophrenia migraine and epilepsy
Strength : 10 mg 25 mg
Dosage form: tablet encapsulated tablet

Study burden and risks

Procedures: pain, light bleeding, heamatoma and possibly an infection.

Contacts

Public
Selecteer

Stationsweg 163
9471 GP Zuidlaren
Nederland
Scientific

Selecteer

Stationsweg 163
9471 GP Zuidlaren
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy male subjects
24-45 yrs, inclusive
22-30 kg/m2, inclusive

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/Aids. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters blood in the 10 months preceding the start of the study.

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):	19-05-2010
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Olanzapine
Generic name:	Olanzapine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Topiramate
Generic name:	Topamax
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	20-04-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	26-04-2010
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
EudraCT	EUCTR2010-019664-37-NL
CCMO	NL32196.056.10