Randomised, duoble-blind, placebo-controlled, 3-way crossover study to investigate the effect of 10 mg Lu AA21004 and 30 mg mirtazapine on actual driving performance, psychomotor function and cognitive function in healthy subjects

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The objective of the current study is to investigate the possible effects on driving ability of a new anti-depressant (10 mg Lu AA21004) after 1 day of dosing and after 15 days of dosing. These effects will be compared to those of mirtazapine (30 mg…

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

Summary

ID

NL-OMON33491

Source
ToetsingOnline

Brief title
Lu AA21004 and driving performance

Condition

- Other condition

Synonym
depression; anxiety disorders

Health condition

n.v.t. onderzoek betreft gezonde vrijwilligers

Research involving
Human

Sponsors and support

Primary sponsor: Lundbeck
Source(s) of monetary or material Support: H. Lundbeck A/S

Intervention

Keyword: driving performance, Lu AA21004, mirtazapine, placebo-controlled

Outcome measures

Primary outcome

to compare the effects of 10 mg Lu AA21004 and placebo on actual driving performance in healthy subjects, following the first dose and at steady-state, as measured by standard deviation of lateral position (SDLP) during an on-the-road driving test

Secondary outcome

*to compare the effects of 30 mg mirtazapine and placebo on actual driving performance in healthy subjects, following the first dose and at steady-state, as measured by SDLP during an on-the-road driving test

*to compare the effects of 10 mg Lu AA21004 and 30 mg mirtazapine on actual driving performance in healthy subjects, following the first dose and at steady-state, as measured by SDLP during an on-the-road driving test

*to assess the effects of 10 mg Lu AA21004 and 30 mg mirtazapine on standard deviation of speed (SDS) measured during an on-the-road driving test following

the first dose and at steady-state

*to assess on a explorative basis the effects of 10 mg Lu AA21004 and 30 mg

mirtazapine on psychomotor and cognitive functions, following the first dose

and at steady-state

Study description

Background summary

Depression is a widespread disease which also results in a widespread use of antidepressants. It is well known that these drugs, that cross the blood-brain barrier, can cause sedation which then can have a negative influence on daily functioning of patients. This is of special importance for patients who drive a car and for whom a drop in their alertness can be of a danger to themselves and to others.
Because there is a great potential risk of non-compliance when patients are obliged to refrain from driving a car it is of great importance to investigate the actual influence of these drugs on driving performance. This with the purpose to inform patients well about the potential risks.
Lu AA21004 is new drug in development for the treatment of depression. The purpose of this study is to gather more information about the sedative effects of 10 mg Lu AA21004 after 1 dosing and to investigate the effects after multiple dosing (15).

Study objective

The objective of the current study is to investigate the possible effects on driving ability of a new anti-depressant (10 mg Lu AA21004) after 1 day of dosing and after 15 days of dosing. These effects will be compared to those of mirtazapine (30 mg) and placebo.

Study design

Randomised, double-blind, placebo-controled, 3-way crossover study.
- 21 volunteers, age between 21 and 45, will be randomly assigned to 1 of the treatment orders.
- The study consists of 3 treatment periods each lasting 16 days. On days 1 till 15 the volunteer takes the medication. On day 2 and 16 of each period the driving ability, psychomotor functions and cognitive functions will be tested. Between each treatment period will be a wash-out period of at least 14 days.
- Before participation subjects are medically screened and all the tests used

in the study are practiced.
- On each testday the computertests are conducted 12 hours after dosing. The driving test is conducted 13,5 hours after dosing.

Intervention

The studied treatments consist of multiple dosing (1 dosing per day for 15 consecutive days) of 10 mg Lu AA21004, 30 mg mirtazapine and placebo. Administration of the medication is double-blind. Between each treatment period will be a wash-out period of at least 14 days.

Study burden and risks

The total amount of time invested in the study by each subject will be approximately 41 hours. Before final participation a medical screening will take place, during which, besides a physical check-up, an urinesample and a bloodsample (12 ml) will be collected. Also an ECG will be made. Before start of the treatment periods 2 training sessions are planned during which all the used tests are practiced. Each subject comes to the university on day 1 of each treatment period to collect the medication for that period. Female subjects will be tested for pregnancy. For this purpose a bloodsample (8 ml) will be taken. This test is repeated on day 16 of each period. The subject takes the medication in the evening at home during each testperiod for 15 days and comes during each period to the university on days 2 and 16 to be tested. Each of these visits will last 4 hours. On each testday a bloodsample (8 ml) will be taken to determine the amount of study medication present in the body. The night before a testday subjects have to make sure they sleep well. Alcohol-, and caffeine intake are limited during participation. Besides the fact that it is possible that side effects will occur and that subjects are advised not to drive a car on their on own during testperiods (until at least 48 hours after last dosing) there are no considerable risks involved in participation.

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

healthy
age between 21 and 45 years
BMI between 19 and 29 kg/m2
possession of a valid driving licence for at least 3 years
driving experience at least 5000 km per year on average

Exclusion criteria

use of other medication (except anticonception or paracetamol)
pregnancy
smoking
use of drugs
excessive use of alcohol and caffein

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2009
Enrollment:	21
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Lu AA21004
Generic name:	Lu AA21004
Product type:	Medicine
Brand name:	Mirtazapine Krka filmcoated tablets
Generic name:	mirtazapine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	23-03-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	29-05-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2008-005267-34-NL
Other	N/A
CCMO	NL27536.068.09