Thorough QT/QTc Study of 2 Doses of ADASUVE® in Healthy Volunteers

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

Summary

ID

NL-OMON38911

Source
ToetsingOnline

Brief title
ADASUVE® QT/QTc Study

Condition

- Other condition

Synonym
commotion, fash

Health condition

Agitatie

Research involving
Human

Sponsors and support

Primary sponsor: Alexza Pharmaceuticals, Inc.
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: ADASUVE®, agitation, loxapine

Outcome measures

Primary outcome

Pharmacokinetics: Plasma concentrations, pharmacokinetic parameters

Safety: Adverse events, vital signs, ECG-parameters, laboratory parameters,

physical examination

Secondary outcome

n/a

Study description

Background summary

Loxapine is a registered drug that is used for the treatment of agitation. Agitation is an emotional state of excitement or restlessness that is a severe complication of many chronic mental illnesses, including schizophrenia and dementia.
In this study loxapine will be administered via a registered oral inhalator (ADASUVE).
In addition, moxifloxacin, a registered drug that is used for the treatment of a number of bacterial infections, will be administered.

Study objective

The purpose of the study is to investigate the maximum effect of ADASUVE on repolarization of the heart. This is the process where the cells of the heart muscle recharge again after contraction. If this process is strongly slowed down, (potentially risky) abnormalities of the heart rhythm may occur.
In addition, it will be investigated how quickly and to what extent ADASUVE is

absorbed and eliminated from the body (this is called pharmacokinetics).

Study design

This is a single center, randomized, double-blind, double dummy, 2 dose, 3 period, active and placebo controlled QT/QTc and pharmacokinetic study of ADASUVE in healthy volunteers.

Intervention

All subjects will be exposed to 3 different treatments.
A Inhalator: 10 mg ADASUVE, twice daily + Oral: Placebo, once daily
B Inhalator: Placebo, twice daily + Oral: Placebo, once daily
C Inhalator: Placebo, twice daily + Oral: 400 mg Moxifloxacin, once daily

In period 1, 2 and 3 the subjects will be randomly assigned to treatment A, B and C.

Study burden and risks

- possible side-effects as decribed under E9
- venipunctures and blood draws via cannula
- screening and follow-up visit
- admission to the clinic
- study activities: physical examination, ECG, blood pressure and heart rate measurements, vital signs and holter

Contacts

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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

- healthy male or female (females with child bearing potential have to use an effective method of contraception)
- between 18 and 65 years of age, inclusive
- BMI between 18 and 32 kg/m2, inclusive
- no smoking during at least 30 days prior to the screening

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 3 months from the start of the study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2013
Enrollment:	48
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ADASUVE
Generic name:	loxapine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Avelox
Generic name:	moxifloxacin
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	22-04-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	02-05-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	24-05-2013
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	03-06-2013
Application type:	Amendment
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	EUCTR2013-001317-32-NL
CCMO	NL44498.056.13