A twenty-six weeks, open-label extension trial to evaluate safety and efficacy of Org 50081 in outpatients with chronic primary insomnia who completed clinical trial protocol 21106

Published: 20-01-2009
Last updated: 06-05-2024

To investigate safety and tolerability and to collect exploratory efficacy data of long-term treatment with Org 50081 in adult patients with chronic primary insomnia.

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

Summary

ID

NL-OMON33547

Source
ToetsingOnline

Brief title
Extension trial of protocol 21106

Condition

- Other condition

Synonym
insomnia, sleeplessness

Health condition

slaapstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Schering-Plough
Source(s) of monetary or material Support: door de opdrachtgever

Intervention

Keyword: Adult, Insomnia, Safety, Tolerability

Outcome measures

Primary outcome

To investigate safety and tolerability of long-term treatment with Org 50081 in

adult patients with chronic primary insomnia.

Secondary outcome

To collect exploratory efficacy data of long-term treatment with Org 50081 in

adult patients with chronic primary insomnia.

Study description

Background summary

Org 50081 is the maleate salt of the S-enantiomer (Org 4420) of the racemic mixture mirtazapine. Several preclinical and clinical studies have demonstrated sleep-promoting effects of mirtazapine. Increases in sleep efficiency, increases in total sleep time and slow wave sleep, and shorter sleep latency have been observed in patients with major depressive disorder, primary insomnia and in healthy subjects. A dosoe-finding trial with Org 50081 has been performed in 60 patients with primary insomnia to demonstrate superiority of treatment with Org 50081 compared to placebo on Total Sleep Time as measured by polysomnography. Secondary objectives were to investigate dose-response, safety and tolerabilityy and hangover effects after two days of treatment with Org 50081. The fact that sleep promoting effects of Org 50081 may be primarily related to deep stages of sleep and are exerted through a different pharmacological action than that of benzodiazepines makes these effects interesting from both a pharmacological and clinical point of view. Worldwide,

most sleep promoting medicines used in clinical practice act at the benzodiazepine receptor site. Adverse drug reactions related to benzodiazepines, such as tolerance, dependence, addiction, withdrawal and rebound phenomena, have led to a steady decline in the prescription of benzodiazepine hypnotics over the last decade. Consequently, pharmacotherapy has shifted gradually from classical benzodiapzepines to new benzodiazepine agonists such as zolpidem or zaleplon. Since the newer hypnotics also exert their mode of action via the GABA system, they are still associated with abuse potential and have been shown to promote the risk of addiction. Unlike other hypnotics currently available, Org 50081 does not exert its action through the GABA receptors. Org 50081 is not expected to have abuse potential. Over the past 10 years, there has been an increasing use of sedating antidepressants for the symptomatic treatment of insomnia, despite the paucity of data on the efficacy of these drugs in treating insomnia. Tricyclic antidepressants, trazodone, nefazodone and mirtazapine are considered to be pharmacotherapeutic candidates for treating insomnia though they are not approved for this indication.

Study objective

To investigate safety and tolerability and to collect exploratory efficacy data of long-term treatment with Org 50081 in adult patients with chronic primary insomnia.

Study design

This trial is a 26-week, open-label extension trial to investigate safety and explore efficacy of Org 50081 in subjects who have completed tral 21106. Subjects who have completed trial 21106 and are willing to continue treatment with Org 50081, can participate in trial 176003 after the informed consent is signed.
The trial consists of a 26 week period of open-label treatment with 4.5 mg Org 50081 and a follow-up period. Subjects will be asked at the Week 22 visit of trial 21106 to consider participating in the extension trial. The start of trial 176003 coincides with visit 10 (Week 27) of trial 21106 when first 176003 trial medication is dispensed. At this time point informed consent should be signed. Subjects who participate in trial 176003 will not participate in the 7 day follow-up visit and the 30-day follow-up contact in trial 21106.
If the subject fulfills all selection criteria at Day 1, the subject will have open-label medication assigned. In the evening of Day 1, the first trial medication should be taken. This open-label treatment period lasts 26 weeks during which the subject returns to the clinic for a visit after 2 weeks and next every 4 weeks (+/- 3 days).

The treatment period will be followed by a follow-up period, during which no trial medication will be administered. A follow-up visit will take place 7 days

after discontinuation of trial medication for assessment of any (S)AEs. In addition, a telephone call should be scheduled 30 days after the week 26 visit or 30 days after premature discontinuation to follow up on any SAEs related to the trial or occuring after the last intake of active medication.

Study burden and risks

Subjects participating in this extension trial will be treated during 26 weeks with 4.5 mg Org 50081. The discomfort consists mainly out of 9 visits to the clinic (30 days after the 9th visit the subject will be contacted by telephone to follow up on any SAEs occuring after the follow up visit), rlectronic diary, questionnaires, urine and bloodsamples, physical examination and ECGs. The subjects will get extensively check ups, a lot of information and a compensation for costs for time, eventual discomforts and traveling.

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

sign written informed consent
completed trial 21106 (i.e. completed 26 weeks of treatment and finished the 7-day discontinuation period)

Exclusion criteria

any (serious) adverse event, medical condition or required concomitant medication deemed relevant for exclusion in trial 21106, as judged by the investigator
were significantly non compliant with protocol criteria and procedures of trial 21106, as judged by the investigator
pregnancy

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2009
Enrollment:	16
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nog niet bekend

Generic name:	esmirtazapine maleate

Ethics review

Approved WMO Date:	20-01-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	13-02-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-03-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	29-06-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2007-005237-10-NL
CCMO	NL24090.040.09
Other	zie www.organon-trials.com