Open Label Study of the Effect of Daily Treatment with MPC-7869 in Subjects with Dementia of the Alzheimer*s Type.

Published: 28-12-2007
Last updated: 10-05-2024

Safety-evaluation in case of long term daily usage of MPC-7869. In this Open Label Study , with regard to the safety of MPC-7869, attention will be paid to the amount of AE*s, the physical examinations of subjects, the research of vital functions,...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Dementia and amnestic conditions
Study type	Observational non invasive

Summary

ID

NL-OMON31593

Source
ToetsingOnline

Brief title
Alzheimer's disease

Condition

- Dementia and amnestic conditions

Synonym
Alzheimer's disease, Dementia

Research involving
Human

Sponsors and support

Primary sponsor: Myriad Pharmaceuticals, Inc
Source(s) of monetary or material Support: Myriad Pharmaceuticals;Inc.

Intervention

Keyword: Alzheimer type., Dementia

Outcome measures

Primary outcome

Safety effects: this includes the amount of Adverse events (AE*s), changes at

physical examinations and results of the clinical laboratory tests.

Secondary outcome

N.a.

Study description

Background summary

Hypothesis: treatment with MPC-7869, applying to a dose of 800 mgr. BID, will delay the cognitive and functional decline in case of a mild dementia of the Alzheimer's type.

Study objective

Safety-evaluation in case of long term daily usage of MPC-7869.
In this Open Label Study , with regard to the safety of MPC-7869, attention will be paid to the amount of AE*s, the physical examinations of subjects, the research of vital functions, the taking of ECG*s and the clinical laboratory tests. (ref. Protocol, page 28, safety; 10.3).

Study design

An Open Label Study into the effect of the daily treatment of MPC-7869 of subjects with the Alzheimer-type dementia.
All subjects will receive MPC-7869.
Subjects have completed the Myriad MPC-7869 study without protocol violations.

Study burden and risks

Blood sampling takes place every three months, during each clinical visit.
The risks of the patient are the risks of blood sampling, and possible side

effects or undesirable effects of study drugs.

Subjects will undergo a physical examination. An ECG scan will be taken, vital functions will be registered. Blood sampling will be done for haematological tests. An urine sample has to be brought along.

The risk of possible side-effects and undesired effects of the study medication is acceptable, in comparison with existing treatment; this result applies to the degree that it has been researched. Also considering that there aren*t many treatment possibilities for this type of patients.

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

1. Completed, without protocol violations, a Myriad Pharmaceuticals, Inc MPC-7869 clinical trial for Alzheimer's disease.
2. Have had a diagnosis of dementia according to the Diagnostic and Statistical Manual of Mental Disorders * Fourth Edition (text revised) (DSM IV [TR]), as described in Appendix B, and meet the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer*s Disease and Related Disorders Association (NINCDS-ADRDA) criteria for probable Alzheimer*s disease, as described in Appendix C.
3. Have a computed tomography (CT) or magnetic resonance imaging (MRI) within the past 12 months, demonstrating absence of clinically significant focal intracranial pathology. If no scan is available in the previous 12 months, then a CT or MRI scan will be obtained.
4. Have a screening MMSE score *20 and *26.
5. Have a screening Modified Hachinski Ischaemic score < 4.
6. Men or women ages * 55 years and living in the community at the time of enrollment (ie, not living in a rest home or nursing care facility).
7. Subjects must have a reliable caregiver.

Exclusion criteria

1. Current evidence or history in the past 2 years of epilepsy, focal brain lesion, head injury with loss of consciousness and/or immediate confusion after the injuries, or DSM-IV (TR) criteria for any major psychiatric disorder including psychosis, major depression, bipolar disorder, alcohol or substance abuse.
2. History of hypersensitivity to flurbiprofen or other NSAIDs, including COX-2 specific inhibitors.
3. Documented evidence of active gastric or duodenal ulcer disease within the past 3 months.
4. Chronic or acute renal, hepatic or metabolic disorder .
5. Uncontrolled cardiac conditions (New York Heart Association Class III or IV)
6. History of NSAID associated ulcers.

Study design

Design

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

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-07-2008
Enrollment:	11
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-12-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	13-06-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	EUCTR2007-003362-17-NL
CCMO	NL20362.029.07