Clinical effects of low dose pipamperone (Dipiperone) versus placebo on cognitive functions of elderly patients suffering from cognitive dysfunction, admitted at a general hospital.

Published: 12-02-2007
Last updated: 09-05-2024

To asses the clinical effect of low dose pipamperone on cognitive functions of elderly patients suffering from cognitive dysfunction.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON30224

Source
ToetsingOnline

Brief title
Effects of pipamperone on cognitive functions of the elderly

Condition

- Cognitive and attention disorders and disturbances

Synonym
cognitive dysfunction; confusion

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Drenthe (Assen)
Source(s) of monetary or material Support: GGZ Drenthe

Intervention

Keyword: cognitive dysfunction, cognitive functions, elderly patients, pipamperone

Outcome measures

Primary outcome

The results of the first and second MMSE will be taken into account, the

positive or negative difference between these two will represent the effect of

pipamperone on the cognitive functions of elderly people admitted at a general

hospital. The doubleblind randomisation will rule out any effects caused by,

e.g., physical recovery.

Secondary outcome

Not applicable.

Study description

Background summary

Pipamperone (Dipiperone) is registered in the Netherlands for treating psychosis, sleeping disorders in case of schizofrenic psychosis and for treating children with a psychiatric disorder who show severe agressive behaviour.

Pipamperone has a slight effect on the D2 receptor (blockage), on the alpha2 receptor (blockage), the ACh receptor (blockage), a stronger effect on the H1 receptor and a significant strong effect on the serotonin receptor.

Elderly patients admitted at hospital often show cognitive dysfunction on behalf of their illness, disturbance of their familiar daily routine, change of surroundings and medical interventions. Based on experience, we believe that low dose pipamperon has a positive effect on cognitive functions of these

patients. Yet, there is no scientific evidence to support these beliefs.

Study objective

To asses the clinical effect of low dose pipamperone on cognitive functions of elderly patients suffering from cognitive dysfunction.

Study design

The study will be double blind randomized controlled. Patients will be treated by pipamperone drops or placebo (liquid drops, in appearance not different from the pipamperone drops) to be able to rule out favourable effects on cognitive functions provided by physical recovery. The pharmacy will provide the pipamperone drops and placebo and will randomize the patient-placebo or patient-pipamperone match.

Intervention

A Mini Mental State Examination (MMSE) will be taken on the same day that patients are admitted or shortly after. This test will assess the cognitive (dys)function of patients.

When a patient meets the criteria of inclusion, he or she will be administered 10 drops of pipamperone in the evening (40mg/ml = 20 mg).

Another MMSE will be taken before the patient will leave the hospital. At least 4 days must have been passed between the first time the MMSE is taken and the second MMSE is taken.

Study burden and risks

Patients will be treated by pipamperone or placebo. Pipamperone will be prescribed in a very low dose of which adverse effects will not be expected, thus excluding any harm on account of the patient.

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

- Patients who are clinically admitted (at the Wilhelmina Hospital in Assen, The Netherlands);
- Patients who score a minimum of 17 points and a maximum of 24 points on the Mini Mental State Examination (MMSE);
- The prognosis of the illness is favourable (patients are not terminally ill);
- Patients (or their legal representative) have given their written permission for participation in the study.

Exclusion criteria

- Patients who are suffering from a terminal illness, which is expected to be fatal on short term;
- There is a medical objection to treatment with pipamperone, e.g. the patient is suffering from Parkinson's disease, spastic paralysis, depression of the central nervous system, lesions of the basal ganglia, (severe) cardiovascular disease, severe organic cerebral disease or epilepsy.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2008
Enrollment:	88
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	dipiperone
Generic name:	pipamperone
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	12-02-2007
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Approved WMO

Date:	29-01-2008
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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	EUCTR2006-005313-35-NL
CCMO	NL14548.097.06