The effects of melatonin in the treatment of delirium

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To Evaluate the differences between teh length of delirium in the anti-psychotics+ melatonin group and the anti-psychotics + placebo group.

Ethical review	Approved WMO
Status	Pending
Health condition type	Deliria (incl confusion)
Study type	Interventional

Summary

ID

NL-OMON32448

Source
ToetsingOnline

Brief title
MAPLE B

Condition

- Deliria (incl confusion)

Synonym
acute confusion, psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Uit AMC geld tnv Sophia de Rooij

Intervention

Keyword: Delirium, Elderly, Melatonin, Treatment

Outcome measures

Primary outcome

Evaluate possible differences in duration of delirium between the anti-psychotics + melatonin group and the anti-psychotics + placebo group.

Secondary outcome

* Evaluate possible differences in severity of delirium between the anti-psychotics+ melatonin group and the anti-psychotics + placebo group.

* Compare possible differences in the length of hospital stay in delirious patients in the anti-psychotics + melatonin group or anti-psychotics + placebo group.

* Evaluate possible differences in the total dose of additional benzodiazepines used to treat delirium in both the anti-psychotics + melatonin group and the anti-psychotics + placebo group.

* Evaluate possible differences in the total dose of haloperidol used during the period of delirium in both the anti-psychotics + melatonin group and the anti-psychotics + placebo group.

* Evaluate the possible effects of delirium and of melatonin therapy on cognitive decline 3 months and 12 months after hospital admission.

* Evaluate possible effects of delirium and of melatonin therapy on functional decline, measured by grip-strength and by KATZ questionnaire.

Study description

Background summary

Delirium is a frequent problem during hospital admittance in the elderly patient. The syndrome is characterized by symptoms of disturbed consciousness, concentration and cognition which all have a fluctuating course, as well as symptoms of disturbed sleeping patterns with awakening at night and sleepiness at daytime. Delirium is a serious condition, associated with a three-time increased mortality risk, higher institutionalisation rate and increased health care costs. The disturbed sleeping patterns in patients with delirium might be associated with a disturbed circadian rhythm of melatonin secretion. We propose that treatment of delirium with melatonin, in addition to conventional treatment with anti-psychotics, might be effective in reducing the duration of delirium, which could result in a reduced length of hospital stay and its associated costs.

Study objective

To Evaluate the differences between teh length of delirium in the anti-psychotics+ melatonin group and the anti-psychotics + placebo group.

Study design

A randomized, double blind, placebo controlled trial.

Intervention

Treatment of patients with delirium with melatonin or placebo for a maximum of 10 ten days

Study burden and risks

Scientific benefits
Haloperidol and clozapine are recommended as first line drugs in the treatment of delirium and is, apart from delirium, effective in the treatment of patients with psychosis or psychotic depression. Both anti-psychotics however are known to have neuro-psychiatric and/or cardiovascular side-effects related to therapy, especially in frail elderly patients. If melatonin helps treating delirium by restoring circadian rhythm, in the future less haloperidol will be needed to treat delirium. Furthermore, by its sleep promoting effects, melatonin might also decrease the need for additional benzodiazepines in the treatment of delirium.
If such an observation could be demonstrated from this study it challenges the general conclusion that haloperidol is not effective enough and suggests that

additional melatonin may be more beneficial in treatment of delirium symptoms.
Individual benefits
Possible benefits for subjects participating in this study are that delirium and predisposing risk factors such as cognitive impairment will be assessed. Also, they will be closely monitored for delirium during this study. The symptoms of delirium and potential ADE*s are well controlled during the study. Considering that the study population is at risk for (new) psychiatric illness careful and close post-discharge follow up will be provided.

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] Age 65 years or older
2] Acute hospital admission at medical ward

3] Patients diagnosed with delirium for which anti-psychotic therapy is needed.
4] Patients must be willing and medically able to receive therapy according to the protocol for the duration of the study
5] Written informed consent must be obtained

Exclusion criteria

1] Patients on medication that can*t speak or understand Dutch
2] Patients diagnosed with delirium who have received anti-psychotics longer than 24 hours.
3] Patients with a clinical diagnosis of hypoactive delirium

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	702
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Melatonin
Generic name:	N-acetyl-5-methoxytryptamine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	01-04-2009
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	EUCTR2008-006452-22-NL
CCMO	NL25404.018.08