The effects of melatonin in the treatment of delirium-
a double blind, randomized, placebo-controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21861

Source
NTR

Brief title
MAPLE B

Health condition

delirium, medically-ill, elderly patients.
delier, interne-aandoeningen, oudere patienten.

Sponsors and support

Primary sponsor: Academic Medical Center
Amsterdam
Source(s) of monetary or material Support: Academic Medical Center

Intervention

Outcome measures

Primary outcome

Evaluate possible differences in duration of delirium between patients receiving either anti-psychotics + melatonin or anti-psychotics + placebo.

Secondary outcome

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

2. Compare possible differences in the length of hospital stay in delirious patients in the anti-psychotic + melatonin group or anti-psychotic + placebo group;

3. 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;

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

5. Evaluate the possible effects of delirium and of melatonin therapy on cognitive function 3 months and 12 months after hospital admission;

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

Study description

Background summary

N/A

Study objective

To compare the differences in duration of delirium in delirious patients receiving anti-psychotic therapy + melatonin or anti-psychotic therapy + placebo.

Study design

During admission on each day of the study until the delirium is resolved with a maximum of twelve days. Three months and twelve months after discharge from the hospital.

Intervention

patients receive anti-psychotics and melatonin or antipsychotics and placebo.

Contacts

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Eligibility criteria

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2009
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-02-2009
Application type:	First submission

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
NTR-new	NL1578
NTR-old	NTR1657
Other	EudraCTnumber : 2008-006452-22
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A