MAPLE A
(Melatonin Against PLacebo in Elderly patients).

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22152

Source
Nationaal Trial Register

Brief title
MAPLE A

Health condition

Delirium
Hip Fracture
Elderly

Sponsors and support

Primary sponsor: Sponsor is performer
Source(s) of monetary or material Support: Fund=initiator= sponsor

Intervention

Outcome measures

Primary outcome

Delirium diagnosed within 8 days after start of the study medication.

Secondary outcome

1. Severity and duration of delirium in the treatment and in the control arm.

2. Evaluate differences in subtypes of delirium in the treatment and in the control arm.

3. Evaluate differences in length of hospital stay in the treatment and in the control arm.

4. Compare the additional use of benzodiazepines during delirium in the treatment and in the control arm.

5. Compare the total dose of haloperidol used during delirium in the treatment and in the control arm.

6. Evaluate differences in in-hospital complications, defined as hospital related infections, decubitus and malnutrition in patients the treatment and in the control arm.

7. Evaluate differences in cognitive and functional decline at 12 months after hospital discharge in the treatment and in the control arm.

8. Evaluate differences in mortality during hospital stay and after 12 months follow-up in the treatment and in the control arm.

9. Evaluate differences in DNA profile in delirious and non-delirious patients.

Study description

Background summary

N/A

Study objective

Hypothesis is that elderly patients, acutely admitted for hip fracture, treated with melatonin for 5 days will experience less delirium than patients treated with placebo.

Study design

At inclusion patiente will be asked to fill in different questionaire's to asses cognitive function and activities of daily living (KATZ score, IQ-scoree, MMSE, hand-grip strenght).

At 3 months and 12 months after hospital admission patients will be visited at home for assesment of cognitive and functional decline.

Intervention

Patients included in the MAPLE A stduy will be assigned to receive either melatonin 3 mg or placebo for 5 consequtive days.
Daily check-up will take place for evaluation of delirious symptoms, using the CAM score.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age: 65 years or older;

2. Acute admission for surgical repair of hip-fracture;

3. Patiente must be willing and medically able to take the study medication;

4. Patients must be able to give informed consent.

Exclusion criteria

1. Patients who can't speak / understand Dutch;

2. Patients transferred for surgical repair from another hospital.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2008
Enrollment:	340
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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	NL1506
NTR-old	NTR1576
Other	2008-000996-57 : EudraCT
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A