The effects of melatonin versus placebo on post-operative delirium (POD) in hip fracture patients – a randomized double-blind trial

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23033

Source
Nationaal Trial Register

Brief title
MAPLE

Health condition

Melatonin, delirium, prevention, hipfractures

Melatonine, delirium, preventie, heupfracturen

Sponsors and support

Primary sponsor: S.E. de Rooij / Academic Medical Centre Amsterdam
Academic Medical Center
Meibergdreef 9
1105 AZ Amsterdam
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Tel. (31)205665991
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Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

Primary endpoint will be the occurrence of POD diagnosed with the Confusion Assessement Method (CAM-score) within 5 days after surgery.

Secondary outcome

1. Whether visual assessment of SPECT scans may reveal perfusion abnormalities in frontal or parietal cerebral perfusion abnormalities in patients with and without POD using placebo and in (non)-delirious patients using melatonin.

2. Differences in plasma melatonin concentrations in delirious and non-delirious patients using placebo and in patients using melatonin

3. Severity and duration of POD in placebo and melatonin group

4. Both hospital and post-discharge complications in (non) delirious patients using placebo and melatonin

Study description

Study objective

Treatment with 3 mg melatonin daily will reduce the incidence of postoperative delirium in patients with hipfractures over 65 years of age.

Study design

Patiente will be included before surgical treatment for hip- or femoral fracture.

Melatonin will be given once daily for day 1 untill day 5 postoperative.

We will measure melatonin bloodlevels on day 2 and day 5 postoperative.

Intervention

After informed consent and after surgical repair of the hip fracture, patients are randomized to receive melatonin 3 mg or placebo in the evening with a maximum of 5 days. After reaching g the primary endpoint, ie delirium, the patient will start with haloperidol and

treatment with melatonin or placebo will be ended.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age: 65 yrs or older

2. Unplanned surgical repair of hip or femoral fracture

3. Patients must be willing and medically able to receive therapy according to the protocol for the duration of the study

Exclusion criteria

1. Age: under 65 yrs

2. Delirium:pre-operative

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):	01-05-2008
Enrollment:	175
Type:	Anticipated

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	NL1180
NTR-old	NTR1225
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A