# Melatonin and type of delirium: is there an association?

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Primary questions: 1) Is there a significant difference between the postoperative levels of 6-sulfatoxymelatonin (6-SMT, metabolite of melatonine) in 24 hour urine samples, in elderly patients with traumatic hip fractures, with and without a...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Deliria (incl confusion) |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON50685

**Source**
ToetsingOnline

**Brief title**
Melatonin and delirium

### Condition

- Deliria (incl confusion)

**Synonym**
confusion, delirium

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Elisabeth-Tweesteden ziekenhuis
**Source(s) of monetary or material Support:** Vakgroep Klinische Geriatrie TweeSteden Ziekenhuis. Wetenschapscommissie TweeSteden Ziekenhuis.

## Intervention

**Keyword:** Delirium, Melatonin

## Outcome measures

### Primary outcome

6-SMT (metabolite of melatonin) levels in 24 hour urine samples in patients

with and without delirium (hyperactive, mixed, hypoactive).

### Secondary outcome

6-SMT (metabolite of melatonin) levels in 24 hour urine samples, in association

with the level of postoperative pain, measured using the Visual Analogue Scale

(VAS) and the use of pain medication, in patients without delirium.

# Study description

### Background summary

Elderly patients, admitted with a traumatic hip fracture, are at an increased risk for developing a delirium. The exact mechanisms behind the pathophysiology of delirium remain uncertain. The pineal gland hormone melatonin may play a significant role, since it is associated with circadian rhythmicity and normal sleep, which is often compromised in patients suffering from a delirium. Furthermore, melatonin might have analgesic effects, which might influence levels of pain post-operatively, another known risk factor for delirium. Only a small number of studies examined the association between type of delirium and melatonin levels, and the relation between melatonin levels and pain scores in elderly patients with traumatic hip fractures. One study examined the association between the type of delirium and 6-SMT (metabolite of melatonin) in 24-hour urine samples. A hyperactive delirium was associated with a decrease of 6-SMT, while a hypoactive delirium was associated with an increase. However, when interpreting these results, the methodological shortcomings and small number of included patient in each group should be taken into account. Several intervention studies preventively prescribing melatonin orally have taken place, and show conflicting results. If there is indeed an association between the type of delirium and the level of melatonin, this could help in distinguishing patients who might and might not respond to treatment with melatonin in future trials.

With this study we want to examine the association between the type of delirium and melatonin levels in elderly patients with a hip fracture. We hypothesize that a hyperactive delirium is associated with lower levels of melatonin, and a hypoactive delirium with relatively higher levels of melatonin, in both saliva and urine. Furthermore, we hypothesize that participants who experience more pain show lower melatonin levels.

## Study objective

Primary questions:
1) Is there a significant difference between the postoperative levels of 6-sulfatoxymelatonin (6-SMT, metabolite of melatonine) in 24 hour urine samples, in elderly patients with traumatic hip fractures, with and without a delirium?
2) Is there an association between type of post-operative delirium (hyperactive, mixed, hypoactive) and postoperatieve 6-SMT levels in 24 hour urine samples, in elderly patients with traumatic hip fractures?

Secondary objectives:
3) Is there an association between the level pain (measured with the Visual Analogue Scale (VAS) and the need for painkillers) and postoperative 6-SMT in 24 hour urine samples, in elderly patients with hip fractures?

## Study design

Single-center cross-sectional study.

## Study burden and risks

Female patients are routinely provided with a urinary tract catheter perioperatively, which we will use to collect the 24 hour urine samples in female participants. Male patients however are not routinely provided with a catheter. The 24 hour urine of male participants without a catheter will be collected either through a urinal or, if the participant is incontinent, a condom catheter. They will be added by the nursing staff.

Participants will be asked to collect another sample of 24 hour urine 6 weeks later, and hand this sample over to the laboratory at the time of regular post-operative follow-up consultation at the (orthopedic) surgeon.

Caregivers will be asked to fill in a short questionnaire about the participant's cognition (IQCODE-N).

The other procedures that are relevant for the study are all part of the routine assessment of elderly patients with a hip fracture in the Elisabeth-TweeSteden hospital, and will not lead to any extra burden.

There is no risk associated with participation.

As patients with dementia are most at risk for developing a delirium, we consider it essential to include them in this study. This ensures that the data is representable. Taking into account the research question, it is also inevitable to include patients with a delirium. Moreover, we think that the total burden of participation is relatively low, also for vulnerable patients,
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## 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

Age 70 years and older
Admitted to the trauma ward in the Elisabeth-TweeSteden hospital for

non-elective hip surery after a traumatic hip fracture

### Exclusion criteria

Patients who are unable to speak and understand the Dutch language

## Study design

### Design

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| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Basic science |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 21-10-2016 |
| Enrollment: | 150 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 08-03-2016 |
| Application type: | First submission |
| Review commission: | METC Brabant (Tilburg) |
| Approved WMO Date: | 21-12-2017 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |

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| Approved WMO Date: | 08-02-2021 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |

# 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 |
|---|---|
| CCMO | NL52387.028.15 |