

# Measuring activity patterns to diagnose a delirium using wrist-actigraphy and Everon monitoring

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To investigate whether the Actiwatch® actigraph and the Everon\* sensor can be helpful in the early diagnosis of a delirium. If both are able to do so, we evaluate which of the two performs best as a delirium screening device.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Deliria (incl confusion)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON35032

### Source

ToetsingOnline

### Brief title

MOVED: Movements of vulnerable elders reveal a delirium

### Condition

- Deliria (incl confusion)

### Synonym

acute confusional state, delirium

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** actigraphy, delirium, elderly with a hip fracture, Everon monitor

## Outcome measures

### Primary outcome

Primary endpoints are the activity patterns and circadian rhythms as measured by the wrist-actigraph and the Everon sensor.

Secondary endpoints are: diagnosis, onset, duration and severity of the delirium, determination of delirium subtype, tolerability of the 2 devices by the patients, and statistics of the activity patterns of the delirious patients and the non-delirious patients.

### Secondary outcome

Secondary endpoints are: diagnosis, onset, duration and severity of the delirium, determination of delirium subtype, tolerability of the 2 devices by the patients, and statistics of the activity patterns of the delirious patients and the non-delirious patients.

## Study description

### Background summary

Elderly patients admitted to the hospital frequently suffer from a delirium. A delirium is a syndrome that is characterized by symptoms of disturbed consciousness, concentration and cognition, and symptoms of disturbed sleeping patterns. In addition, a delirium is highly heterogeneous in clinical presentation. This is represented in the concept of hypoactive, hyperactive and mixed motor subtypes, which states that patients can be classified according to their activity pattern. It is important to distinguish between the subtypes since each of them requires a specific treatment. Subtyping is based on observations and scales without any available golden standard. The diagnosis delirium is therefore frequently missed, especially the hypoactive and mixed

subtypes. Preliminary studies have shown that devices capable of measuring patients\* activity can play a role in the early screening of delirium. We want to investigate whether two specific devices are able to do so, and which of the two devices performs best.

### **Study objective**

To investigate whether the Actiwatch® actigraph and the Everon\* sensor can be helpful in the early diagnosis of a delirium. If both are able to do so, we evaluate which of the two performs best as a delirium screening device.

### **Study design**

An observational cohort study.

### **Study burden and risks**

Patients\* activity patterns will be measured throughout the length of their hospital stay. The Everon\* device is a non-contact sensor that has to be placed under the patient\*s mattress, and hence the patient does not notice its presence. The actigraph is a simple device, the size of a watch, that is placed on the wrist like a watch. Since most people are used to wearing a watch, we do not think that patients perceive the actigraph in any way as uncomfortable. Obviously, there are no risks associated with these devices.

## **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

- \* Patients acutely admitted for unplanned surgical repair of hip fracture
- \* Admitted on the surgical or orthopedic ward
- \* Age 65 years or older
- \* Patients or their primary caregivers must be able to give informed consent

### Exclusion criteria

- \* Patients that can't speak or understand Dutch / English.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-04-2010

Enrollment: 40

Type: Anticipated

## Ethics review

Approved WMO

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
CCMO	NL31530.018.10