

# Pharmacokinetics of midazolam in the elderly on the Intensive Care Unit: a pilot study

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Objective: The primary objective of this study is to evaluate the pharmacokinetics of midazolam in elderly patients (>70 years) admitted to the ICU.

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON45744

### Source

ToetsingOnline

### Brief title

MIKIEL - pilot

### Condition

- Other condition

### Synonym

artificial sleep conditions, Sedation need

### Health condition

Situaties waarbij sedatie op de IC nodig is

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Intensive Care

**Source(s) of monetary or material Support:** Wetenschapsfonds Martini ziekenhuis

## Intervention

**Keyword:** Intensive care, Midazolam, Pharmacokinetics

## Outcome measures

### Primary outcome

Main study parameters/endpoints: The pharmacokinetic profile of midazolam in elderly patients on the ICU.

### Secondary outcome

- To determine the elimination half-life of midazolam in elderly patients on the ICU;
- To determine whether accumulation of midazolam occurs in elderly patients on the ICU;
- To determine the metabolic capacity of the liver by the ratio midazolam/1-hydroxy midazolam in elderly patients on the ICU.
- To gain basic insight in the effect of factors, that are present on the ICU such as: Decreased kidney function, inflammatory state, cardiac function and body mass on the pharmacokinetic profile of midazolam.

## Study description

### Background summary

Rationale: Patients on the Intensive Care Unit (ICU) are often sedated to reduce anxiety and facilitate treatment eg mechanical ventilation. Midazolam is frequently used as a sedative. Physiologic changes by both aging and

critical illness might have their consequences for the pharmacokinetics of midazolam. Both in patients on the ICU and in the elderly, it has been observed that the elimination half-life could be prolonged. To our knowledge no studies are currently available describing the effect of aging on the pharmacokinetics of midazolam, while the percentage elderly patients on the ICU is increasing. Hypothetically, the elimination half-life of midazolam in elderly intensive care patients is double prolonged. In order to optimize sedation adequate dosing administration is required

## **Study objective**

Objective: The primary objective of this study is to evaluate the pharmacokinetics of midazolam in elderly patients (>70 years) admitted to the ICU.

## **Study design**

Study design: Prospective pilot study.

## **Study burden and risks**

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In this study, at least 11 blood samples will be taken in order to determine midazolam levels. The midazolam level will not be used to adjust the dose during the study period and standard care will be provided (determination of bloodlevels will be performed at the end of the study period). The difference between standard treatment and participation in this study consists of collection of at least 11 additional blood samples. Because intensive care patients have an indwelling arterial catheter, this will be of minimal discomfort for the patient.

## **Contacts**

### **Public**

Selecteer

Van Swietenplein 1 1  
Groningen 9728NT  
NL

### **Scientific**

Selecteer

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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 ;

Admitted to the ICU and institution of invasive mechanical ventilation

Intravenously administration of midazolam;

Expected midazolam administration for at least 12 hours;

### Exclusion criteria

Use of CYP3A4 inhibitors or inducers at the start of the study;

o Strong to very strong CYP3A4 inhibitors: boceprevir, clarithromycin, erythromycin, grapefruit juice, indinavir, itraconazole, ketoconazole, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin and voriconazole.

o Strong to very strong CYP3A4 inducers: carbamazepine, dabrafenib, rifampicin and Saint John`s-wort.

Patients participating in another study;

Prescription of other sedatives (except fentanyl);

Patients suffering from cerebral condition, that may influence RASS scores.

## Study design

## Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

## Recruitment

NL

Recruitment status: Will not start

Enrollment: 10

Type: Anticipated

## Ethics review

Not approved

Date: 03-12-2019

Application type: First submission

Review commission: RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

## 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**

CCMO

**ID**

NL65812.099.18