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

Published: 03-12-2019
Last updated: 11-04-2024

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

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	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: ldecreased 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

Van Swietenplein 1 1
Groningen 9728NT

NL

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 inductors 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 inductors: 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	ID
CCMO	NL65812.099.18