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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22131

Source
Nationaal Trial Register

Brief title
MIKIEL

Health condition

Prolonged half-life
Midazolam
Elderly
Intensive care
Pharmacokinetics

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Wetenschappelijk instituut Martiniziekenhuis

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to evaluate the pharmacokinetics of midazolam in elderly patients admitted to the ICU. A time versus midazolam blood level curve, in which RASS level and dose infused is visible, will be created.

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

Study objective

Hypothetically, the elimination half-life of midazolam in elderly intensive care patients is double prolonged.

Study design

A blood sample of 2 mL will be drawn before the start of the therapy. After starting therapy a 2 ml blood sample will be drawn at 6, 12, 18 and 24 hours. Then, every 24 hours a blood sample will be stored until cessation of midazolam therapy (no extra blood drawing; sample originating from standard of care). After finalization, 2ml blood samples are drawn at 0, 3, 6, 12, 18, 24, 30, 36, 48, and 72 hours.

Intervention

None

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

ƒ{ Age >70 years ;

ƒ{

ƒ{ Admitted to the ICU and institution of invasive mechanical ventilation
Intravenously administration of midazolam;

ƒ{ Expected midazolam administration for at least 12 hours;

Exclusion criteria

ƒ{ 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.

ƒ{ Patients participating in another study;

ƒ{ Prescription of other sedatives (except fentanyl);

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2019
Enrollment:	10
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	NL7393
NTR-old	NTR7601
Other	ABR nummer : 65812

Study results