A Randomized Controlled Trial on the effects of midazolam on the quality of postoperative recovery in patients

Published: 07-11-2012
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Does Midazolam improve the quality of postoperative recovery

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39977

Source
ToetsingOnline

Brief title
The effects of midazolam on the quality of postoperative recovery

Condition

- Other condition

Synonym
anxiety

Health condition

Anesthesiologisch

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anxiety, midazolam, postoperative recovery, quality of recovery

Outcome measures

Primary outcome

Quality of postoperative recovery (QoR)

Secondary outcome

Anxiety

Agression

Fatique

Medical fysiological data

Depression

Knowledge on the surgery performed

Somatic symptoms

General Self-Efficacy Scale

Self-Esteem

Study description

Background summary

Anxiolytic premedication isn't standard in hospitals. Although a lot of patiënts are anxious or nervous before an operation. Every person deals differently with this anxiety and forms a resistance. We hypothesise that anxiety before an operation influences the quality of postoperative recovery in a negative way. Therefor by reducing anxiety with a benzodiazepine (known for

reducing anxiety) we think the quality of postoperative recovery will be better.

Study objective

Does Midazolam improve the quality of postoperative recovery

Study design

Randomized Controlled Trial, Double blinded Placebo Controlled

Intervention

Midazolam (dormicum) 3mg

Study burden and risks

It takes 40 minutes for patiënts to fill in all the questionairres. There are no risk related to this study.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3000CA
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3000CA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients operated with a laparotomy in Erasmus MC Rotterdam with a planned postoperative stay for min. 3 days in the hospital

Exclusion criteria

pregnant, benzodiazepine usage, contra-indication for midazolam, mental retardation, non-dutch speeking patients

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-06-2014
Enrollment:	192
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Midazolam
Generic name:	Dormicum
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	07-11-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-06-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2012-003680-21-NL
CCMO	NL41783.078.12

Study results

Date completed:	05-10-2015
Actual enrolment:	192