Putting resistance under the microscope

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Main objectiveLorazepam is frequently used as an anaesthesiological premedication before surgery in order to reduce patients resistance. Does lorazepam also improve the quality of recovery in patients scheduled for day-case-surgery?Secondary...

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

Summary

ID

NL-OMON34255

Source
ToetsingOnline

Brief title
WOL

Condition

- Other condition

Synonym
patients resistance, perioperative resistance

Health condition

De weerstand van de patiënt t.o.v. de operatie

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: lorazepam, recovery, resistance, surgery

Outcome measures

Primary outcome

Quality of recovery, aggression, anxiety, fatigue, depression symptoms.

Secondary outcome

pharmacogenetic background lorazepam

Study description

Background summary

Almost all patients, who undergo a surgery, shrink from the surgery (also called resistance). Resistance expressess itself in anxiety, depression symptoms, aggression, fatigue and somatic symptoms. Determinants; demografic, medical, psychological and genetic features; of resistance can affect the expression of patients resistance.
At this moment it is not standardized to give anxiolytic premedication before day-case-surgery. 19% of day-case-surgery patients want something to reduce preoperative anxiety. We want to design a decision model to answer the question which patients are vulnerable and/of have benefit from receiving preoperative lorazepam.

Study objective

Main objective
Lorazepam is frequently used as an anaesthesiological premedication before surgery in order to reduce patients resistance. Does lorazepam also improve the quality of recovery in patients scheduled for day-case-surgery?

Secondary objective
Developping a prognostic model, which tells us which patients are vulnerable and/of need (lorazepam as) premedication before surgery.

Study design

Randomised Controlled Trial, parallel group, double blind, placebo, controlled

Intervention

One group receives once 1-1.5 mg lorazepam before surgery, depending on body weight. The other group receives once placebo (NaCl) before surgery.

Study burden and risks

Once one blood sample of 10 ml (not extra invasive). Patients have to fill in some not intimidating questionnaires at 4 different moments. This will be about 40 minutes to fill in, scattered over a period of 7 working days.

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

age >= 18 years, day-case surgery patients

Exclusion criteria

Patients with the following features: mental retardation, language barrier.
Patients who undergo the following interventions: surgery of the eye, MDL surgery, ESWL treatment, chronic pain relief treatment.
Patients who take psychofarmaca.
Contra-indications for lorazepam use, like Myasthenia Gravis and liver disease, will be excluded too.

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2010
Enrollment:	400
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ativan

Generic name:	Lorazepam
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-06-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-08-2010
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	EUCTR2010-020332-19-NL
CCMO	NL32535.078.10