the MASTER study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22036

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Coronary bypass, chronic pain, duloxetine, pregabalin, placebo

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Investigator initiated

Intervention

Outcome measures

Primary outcome

- Pain on visual analogue scale (VAS)

- Conditioned pain modulation (CPM)

- STAI (State-Trait Anxiety Inventory)

- PCS (Pain Catastrophizing Scale)

- The Big Five Inventory (BFI)

- Hospital Anxiety and Depression Score (HADS)

Secondary outcome

Chronic pain development

Study description

Background summary

The preoperative balance between anti- and pronociception may play a crucial role in the development of chronic postoperative pain. Improvement of the preoperative nociceptive profile of the patient may reduce the risk of developing postoperative pain. To test this hypothesis this study is designed to study the effect of preoperative administration of duloxetine and pregabalin on the development of chronic postoperative pain.

Study objective

Anti-nociception is an existing or attainable state of pain modulation that can be reached by specific pharmacological agents coupled to individual patterns of pain modulation. Being in, or shifted into anti-nociception state of pain modulation, minimizes pain morbidity.

Study design

1. Conditioned pain modulation (CPM) and offset analgesia (OA) will be measured 2 weeks before surgery and two days before surgery.

2. After surgery we will record pain intensity and analgesic consumption during the first 3-5 days.

3. two-weekly chronic post-operative pain and analgesic use will be pursued for 3 months and once more after one year.

Intervention

Two weeks before elective surgery patients will be treated with duloxetine 60mg, pregabalin 150mg or a placebo.
The influence of these treatments on the endogenous pain control will be evaluated

Contacts

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Eligibility criteria

Inclusion criteria

Patients of either sex with American Society of Anesthesiologists score 1, 2 or 3, aged 18 to 70 years planned to undergo elective surgery involving a sternotomy may be enrolled in the study.

Exclusion criteria

1. Pain scores > 3 (on a 11-point numerical rating scale, NRS) reported for most of the day during the past month (including angina);

2. The presence of any chronic pain disorder;

3. Regular use of analgesics for any purpose, including SNRIs, gabapentinoids, COX inhibitors or NSAIDs during the previous month;

4. Use of MAO-inhibitors within the last 14 days;

5. The presence of narrow-angle glaucoma;

6. Inability to perform psychophysical testing (e.g. in case of cognitive or psychiatric disorders);

7. Patients suffering from cognitive dysfunction;

8. Patients currently treated for depression, or any other mood disorder;

9. Inability to give informed consent;

10. Inability to communicate with the investigators;

11. Known allergies to the study medication:

12. Uncontrolled hypertension (diastolic blood pressure > 100 mmHg).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2015
Enrollment:	500
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-09-2015
Application type:	First submission

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	NL5336
NTR-old	NTR5445
Other	LUMC : P15.018

Study results

Summary results
N/A