Chronic pain after herniorraphy pregabalin versus placebo.

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Treatment with pregabalin (150-600 mg dose) results in a statistically significant improvement in endpoint mean pain score of ¡Ý 1,2 during 8 weeks follow-up relatively to treatment with placebo.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20871

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Patients suffering from chronic pain of neuropathic character after unilateral open inguinal hernia repair.

Sponsors and support

Primary sponsor: Pfizer bv
Source(s) of monetary or material Support: Pfizer bv

Intervention

Outcome measures

Primary outcome

The primary outcome is the mean 11-point numerical pain rating score in both treatment groups at baseline and follow-up.

Secondary outcome

The secondary outcomes are the mean light-touch and thermal QST thresholds between the painful inguinal area and the normal contra-lateral side in patients from both treatment groups at baseline and follow-up.

Study description

Background summary

Summary:
Nowadays, chronic pain mainly as a result of iatrogenic nerve damage is generally considered as the most frequent complication after inguinal hernia surgery. The primary objective of this randomised double-blind placebo-controlled trial is to investigate whether pregabalin (pfizer) reduces pain in patients with chronic pain of neuropathic origin after herniorraphy.

Study objective

Treatment with pregabalin (150-600 mg dose) results in a statistically significant improvement in endpoint mean pain score of ¡Ý 1,2 during 8 weeks follow-up relatively to treatment with placebo.

Study design

N/A

Intervention

Placebo versus Pregabalin.

Contacts

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Eligibility criteria

Inclusion criteria

1. History of unilateral inguinal herniotomy;
2. Establishment of neuropathic character of chronic pain by means the LANSS painscore and DN4 score;
3. Abnormal sensitivity (allodynia, dysesthesia, hypoesthesia or dysesthesia) in or around the incisional area;
4. Duration pain ¡Ý 3 months;
5. Gender: Male;
6. Medial or lateral inguinal hernia;
7. Age >= 18 years;
8. Description III or IIIV of pain interfering with daily activity;
9. VAS score ¡Ý 40 mm on Vas scale on which they indicate ¡®how unpleasant or disturbing the worst pain was that they had today¡;¯
10. Informed consent (addendum V).

Exclusion criteria

1. Participation in another trial;
2. Bilateral hernia;
3. Recurrent hernia;
4. Age < 18 years;
5. Cognitive disfunction;
6. Patient is unable to speak Dutch;
7. Description III or IV of pain interfering with daily activity;
8. Patient classified as American Society of Anaesthesiologist Class 4.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2006
Enrollment:	122
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 30188
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL606
NTR-old	NTR663
CCMO	NL12428.078.06
OMON	NL-OMON30188

Study results

Summary results
N/A