CHRONIC PAIN MANAGEMENT AFTER HERNIORRAPHY PREGABALIN VERSUS PLACEBO

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

Summary

ID

NL-OMON30188

Source
ToetsingOnline

Brief title
CHRONIC PAIN MANAGEMENT AFTER HERNIORRAPHY
PREGABALIN VERSUS PLACEBO

Condition

- Peripheral neuropathies

Synonym
groin pain, Inguinodynia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Pfizer,Pfizer bv

Intervention

Keyword: Chronic pain, Groin pain, Inguinal hernia, Inguinodynia

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

Morbidity associated with surgical treatment of inguinal hernia is mainly chronic postoperative pain. Despite chronic pain was thought to be rare, the reported incidence of chronic pain in recent studies is high. In a critical review of inguinal herniorraphy studies between 1987 and 2000 that adopted pain as primary endpoint, the incidence of some degree of long-term groin pain after surgery was as high as 53 % at 1 year (range, 15 % to 53 %).
According to some studies chronic pain is predominantly neuropathic in character. Recently, as of yet unpublished data by Alfieri et al. suggest that failure to identify the inguinal nerves is significantly correlated with the presence of chronic pain and that the incidence of chronic pain increases proportionally with the number of nerves undetected. Nerve damage can originate iatrogenically during surgery or postoperatively.
In the Netherlands 32,000 inguinal hernias are corrected yearly, of which approximately 90% is made up by males. According to a review by Poobalan et al. yearly a minimum of approximately 5000 patients would suffer from chronic pain 1 year after hernia surgery in the Netherlands[10]. If this new drug proves useful, this could have a wide application.

Study objective

The primary objective of this study is to investigate whether pregabalin at a dose of 150-600 mg twice a day reduces pain in patients with chronic neuropathic pain after herniorraphy. This research question will be answered by testing of the following hypothesis:

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

The secondary objective

- The difference in quantitative sensory testing (QST) thresholds between the painful inguinal area and the normal contra-lateral side in patients of which the chronic pain is treated by pregabalin is clinical significant greater than the difference found in patients of which the chronic pain is treated by placebo

Study design

Patient records are scanned for chronic pain after herniorraphy in the participating centers. Patients that seem to match the selection criteria, are phoned by the principal investigator to confirm the intensity, neuropathic character of the pain and to inform the patient subsequently about the ongoing study. Subsequently, patients are invited for an outpatient visit at the ErasmusMC. During this visit the patient is asked for informed consent after confirmation that the pain is of neuropathic origin by means of the LANSS score. Thereafter the patient is randomized in two groups by the pharmacy. One treatment group will receive a placebo while the other receives pregabaline. Subsequently, the patients will not take any medicines for 1 week (baseline phase) to collect our baseline data. During this phase the patients will complete a diary reflecting their pain and pain-related sleep interference. This diary is based on a 11-point numerical rating scale (0 = *no pain* to 10 = *worst possible pain*; 0 = *pain does not interfere with sleep* to 10 = *pain completely interferes with sleep*).
The medication will be mailed to the patient. After the baseline phase the patient will start medication. The first week of medication the patients receive 2x75 mg pregabalin or placebo. The next week the medication will be increased to 2x150 mg. If necessary the dose can be increased the third week as well to 2x300 mg. The phase during which data will be collected encompasses the 8 week fixed dose period after the titration period of 1,2 or 3 weeks.
Follow-up appointments will be made at 8 weeks after fixed medication is started. Patients are free to refuse participation and choose treatment they prefer at any moment. The number of patients found to be ineligible or refusing to participate in the trial and the motivations/causes are recorded. Patients in are at all times allowed to quit the trial.
Data from both treatment groups will be collected at the following points in time: visit to research nurse; baseline phase (diary); 2 weeks (diary); 4 weeks

(diary); 8 week follow-up appointment; events. Patients who fail to keep their 8 week follow-up appointment will be given the option of a further appointment at a more suitable date.

Intervention

Patients are randomized in two groups by the pharmacy. One treatment group will receive a placebo while the other receives pregabaline.

Study burden and risks

Pregabalin has some advances above the traditionally used drugs. It has a low number needed to treat and an attractive number needed to harm. It can be titrated in a relatively short period. The effect can be estimated in a relatively very short time.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 1738
3000 DR Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 1738
3000 DR Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

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 >= 3 months
5. Gender: Male
6. Medial or lateral inguinal hernia
7. Age >= 18 years
8. Description III or IV of pain interfering with daily activity
9. VAS score >= 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 I or II of pain interfering with daily activity
8. Patient classified as American Society of Anaesthesiologist Class 4

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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2008
Enrollment:	135
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lyrica®
Generic name:	Pregabalin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-11-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-12-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-03-2009
Application type:	Amendment
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

ID: 20871
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2006-002286-40-NL
Other	Nederlands Trial Register (ISRTCN/NCT vooralsnog niet ontvangen)
CCMO	NL12428.078.06
OMON	NL-OMON20871