A randomized double-blind, placebo-controlled, parallel group clinical study of pregabalin in patients with chronic pancreatitis

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The effect of pregabalin treatment on patients with chronic pancreatitis

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON33997

Source
ToetsingOnline

Brief title
The effect of pregabalin treatment in patients with chronic pancreatitis

Condition

- Gastrointestinal inflammatory conditions

Synonym
chronic inflammation of the pancreas, Chronic pancreatitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Universiteitsziekenhuis Aalborg;Denemarken. Afdeling Gastroenterologie;contact: Prof. dr. A. Drewes

Intervention

Keyword: chronic pancreatitis, pain, pregabalin

Outcome measures

Primary outcome

The primary efficacy parameter to be evaluated is pain relief. In the clinical part of the study the effect is assessed as changes in the daily experience of pain, which will be assessed using questionnaires, including the modified brief pain inventory-short form (mBPI-sf), the painDETECT questionnaire and patient global impression of change.

In the experimental part the analgesic effect is assessed as changes in the experimental endpoints (i.e. QST parameters). All changes are compared to baseline recordings.

Secondary outcome

Secondary efficacy parameters are changes in quality of life compared to baseline level. The European Organization for research and treatment of cancer quality of life questionnaire, will be used. Also the tolerability of the drug in this patient population will be compared to placebo.

In the experimental part of the study the slope of the QST stimulus response curves are considered secondary efficacy parameters. The experimental baseline recordings will also be compared to recordings from healthy controls to evaluate general aspects of pain processing in the patient group.

Study description

Background summary

Pain by chronic pancreatitis is hard to treat. For the treatment are different medical and surgical options.
The best attempt to establish clear guidelines for the treatment of chronic pancreatitis is *American Gastroenterological Association Medical Position Statement: Treatment of Pain in Chronic Pancreatitis*. Initial treatment consists of low fat diet and non-narcotic analgesics, which can be supplemented by oral pancreatic enzymes and proton pump inhibitors. If an acceptable level of pain relief is not obtained with these drugs, only opioids remain for the management of pain. Opioids have a number of well-known adverse effects and many patients suffering from chronic pancreatitis have a history of alcoholic abuse making opioids, with their associated abuse potential, less suitable for these patients.
Alternatives to medical treatment exist in the form of nerve blockade, lithotripsy and surgical treatment. However, a considerable part of patients are not suitable for these therapies or their pain returns after medical therapy. Thus the importance of identifying potential new treatment regimes for the treatment of pain in chronic pancreatitis is clear.
Pregabalin is an anti-epileptic and is an analogue of the GABA neurotransmitter. Though the exact working mechanism still needs to be resolved, pregabalin reduces the neuronal sensitivity by binding to an auxiliary subunit (α2-δ) of tension depend calcium channels on central neurons, it works anti-convulsive, analgesic and anxiolitic. The effective dosage is 150-600mg daily. Pregabalin hardly gives any side-effects and is a good addition to the standard treatment of neuropathic pain. The literature describes trials with pain relief by post-herpetic neuralgia and painful polyneuropathies with diabetic mellitus. The influence of pregabaline on pain with chronic pancreatitis hasn*t been described in the literature.

Study objective

The effect of pregabalin treatment on patients with chronic pancreatitis

Study design

This will be a randomized, double-blind, parallel group, placebo-controlled study to investigate the effects of pregabalin on clinical and experimental pain in 30 patients with chronic pancreatitis.

Intervention

During the study, the patients will be randomized to receive placebo or pregabalin (Lyrica®). The maximum daily dose of pregabalin is 300 mg administered twice per day. Pregabalin is titrated in 2 steps: for the first 3 days 75mg BID is administered. From Day 4 to Day 7, 150 mg BID is

administered. From Day 8 to Day 21, 300 mg BID is administered.
If a patient does not tolerate 300mg BID it will be acceptable for them to maintain 150mg BID for the remainder of the study, following discussion and guidance from the investigator.
At the end of the study, patients will undertake a medication taper and will take half their maximum tolerated daily dose of pregabalin for 7 days and then discontinue dosing.

Study burden and risks

Side effects of pregabalin. The risks of the quantitative sensory measurements are negligible.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein zuid 10
6500 HB Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein zuid 10
6500 HB Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Male or female patients between the ages of 18 and 70 years with a diagnosis of chronic pancreatitis, diagnosed using the Marseille-Rome/Cambridge diagnostic criteria. Both diabetic and non-diabetic patients will be allowed to enter the study.
2. The patients must suffer from chronic abdominal pain typical for pancreatitis, meet the criteria for chronic pain (pain >/= 3 days per week in at least 3 months) and must consider their pain as severe enough for medical treatment.
3. Personally signed and dated informed consent document indicating that the patient has been informed of all pertinent aspects of the trial.
4. Patients willing and able to comply with the scheduled visits, treatment plan, laboratory tests and other trial procedures.

Exclusion criteria

1. Patients with evidence or history of medical or surgical disease of importance for this study as judged by investigator.
2. Presence or history of major depression.
3. Patients with previously diagnosed moderate to severe renal impairment. Patients with creatinine values > 2x ULN and/or with a significant change to their normal values should be excluded.
4. Patients with a screening 12-lead ECG demonstrating any of the following: heart rate >100 bpm, QRS duration >120 msec, QTc interval >450 msec, PR interval >210 msec, any clinically significant rhythm abnormality, any evidence of myocardial ischemia or injury.
5. Patients with any clinically significant laboratory abnormalities that in the opinion of the investigator may increase the risk associated with trial participation or may interfere with the interpretation of the trial results.
6. Patients treated with pregabalin (Lyrica®) during the previous 4 months.
7. Treatment with an investigational drug within 4 months preceding the first dose of study medication of importance for this study as judged by investigator.
8. Female patients who are pregnant or lactating, or intend to become pregnant. Male patients who intend to father a child during the course of the study. A pregnancy test will be conducted at visit 1 and 3 to ensure that female patients are not pregnant during the study period.
9. Patients unwilling or unable to comply with the lifestyle guidelines.
10. Patients must not suffer from painful conditions other than chronic pancreatitis.
11. Clinical significant illness within two weeks of participating in this study.
12. Involved in planning or conducting the study.
13. Hypersensitivity to pregabalin or any of its components.

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):	01-10-2009
Enrollment:	30
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	06-02-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-07-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2009-010266-28-NL
ClinicalTrials.gov	NCT00755573
CCMO	NL25636.091.09