Effect of Duloxetine 60 mg Once Daily versus Placebo in Patients with Chronic Low Back Pain

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

Summary

ID

NL-OMON32370

Source
ToetsingOnline

Brief title
F1J-MC-HMGC

Condition

- Other condition

Synonym
chronic low back pain

Health condition

chronische lage rugpijn

Research involving
Human

Sponsors and support

Primary sponsor: Eli Lilly
Source(s) of monetary or material Support: Lilly Nederland BV

Intervention

Keyword: Duloxetine, effect, Phase 3, Placebo

Outcome measures

Primary outcome

The primary objective of this study is to assess the efficacy of duloxetine 60 mg once daily (QD) compared with placebo on the reduction of pain severity as measured by the Brief Pain Inventory (BPI) 24-hour average pain score in patients with chronic low back pain (CLBP) during a 12-week, double-blind treatment period.

Secondary outcome

The secondary gatekeeper objectives are:

• to evaluate duloxetine 60 mg QD versus placebo on patients* perceived improvement as measured by Patient*s Global Impressions of Improvement (PGI-Improvement) (Guy 1976)

• to evaluate duloxetine 60 mg QD versus placebo on the improvement of functioning as measured by the Roland Morris Disability Questionnaire (RMDQ-24) (Roland and Morris 1983).

Study description

Background summary

Chronic low back pain (CLBP) is generally defined as any pain in the low back

that persists for at least 12 weeks. CLBP is one of the most common musculoskeletal disorders in developed countries. Back pain in general affects 70% to 85% of all people at some time in their lives, but 90% of affected individuals recover, typically within 12 weeks. Recovery after 12 weeks is slow and uncertain, and this subset of patients is extremely difficult to treat, to the extent that CLBP and related disability are one of the most common contributors to disability and lost productivity in most industrialized countries (Williams et al.1998; Andersson 1999; Deyo and Weinstein 2001). Treatment varies widely, and can include systemic or local pharmacological treatments, physical therapy, electrotherapy or surgical care. Preliminary indication that duloxetine is likely to be effective in CLBP comes from some of the studies in MDD (Major Depressive Disorder), where back pain was evaluated. Two recently completed 13-week efficacy studies were conducted in patients with CLBP. In the first study the primary endpoint was not achieved, though the pattern of response observed on the primary, as well as a number of secondary efficacy variables, provided a strong suggestion that duloxetine at dosages of 60 mg QD and 120 mg QD might be beneficial in the management of CLBP. The second study provided substantial evidence that daily treatment with duloxetine at doses of 60 mg and 120 mg was safe and effective in the treatment of CLBP. This was demonstrated by significant pain reduction on the primary and most secondary efficacy assessments, as well as safe administration and good tolerability during the study. The current study is being conducted to provide a definitive answer for the use of duloxetine in treating chronic low back pain.

Study objective

The primary objective of this study is to assess the efficacy of duloxetine 60 mg once daily (QD) compared with placebo on the reduction of pain severity as measured by the Brief Pain Inventory (BPI) 24-hour average pain score in patients with chronic low back pain (CLBP) during a 12-week, double-blind treatment period. The secondary gatekeeper objectives are:
• to evaluate duloxetine 60 mg QD versus placebo on patients* perceived improvement as measured by Patient*s Global Impressions of Improvement (PGI-Improvement) (Guy 1976)
• to evaluate duloxetine 60 mg QD versus placebo on the improvement of functioning as measured by the Roland Morris Disability Questionnaire (RMDQ-24) (Roland and Morris 1983).

Study design

Method:
Study F1J-MC-HMGC is a multicenter, randomised, phase III, double-blind, parallel, placebo-controlled comparison trial with 3 study periods. Approximately 400 patients will be randomized (ratio1:1) at Visit 2 to the 2 treatment groups (200 patients per arm).

Study Period I (Screening) is a 1-week screening phase.
Study Period II (Visit 2-Visit 6) is a double-blind treatment phase of approximately 12 weeks, during which patients will be randomly assigned at a 1:1 ratio to either duloxetine 60 mg QD or placebo.
Study Period III is a 1-week taper phase (Visit 301). Patients on placebo who have completed study period II, or who are discontinuing the study after 1 week of treatment will remain on placebo and will enter the 1 week taper phase.

Intervention

Duloxetine 60 mg QD or Placebo

Study burden and risks

Previous studies have shown duloxetine to be a safe drug. Participants will not be subjected to any interventions other than physical examination, ECG, urine sample and blood drawing (for chemical/haematological laboratory investigations). Participants will further be asked to keep an electronic diary and fill out a number of questionnaires during their visits. Therefore, the estimated risks of participation are low. Possible unpleasant experiences include nausea, headaches, dry mouth,somnolence.
The study is divided into 3 periods lasting a total of 14 weeks (after screening). A total of 7 visits will be scheduled, with intervals varying from 1 and 3 weeks.

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

Male or female outpatients at least 18 years of age with a clinical diagnosis of chronic low back pain. Pain must be present on most days for at least 6 months.

Exclusion criteria

Patients with a history of more than 1 low back surgery or history of low back surgery within 12 months prior to study entry. Patients that have received epidural steroids, facet block, nerve block or other invasive procedures aimed to reduce low back pain within 1 month prior to the study. May not have any previous diagnosis of psychosis, bipolar disorder or schizoaffective disorder.

Study design

Design

Study phase:	3
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):	15-09-2008
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	cymbalta + yentreve
Generic name:	Duloxetine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	26-06-2008
Application type:	First submission
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)

Approved WMO

Date:	04-08-2008
Application type:	First submission
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)

Approved WMO

Date:	25-11-2008
Application type:	Amendment
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)

Approved WMO

Date:	03-12-2008
Application type:	Amendment
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)

Approved WMO

Date:	06-03-2009
Application type:	Amendment
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)
Approved WMO Date:	12-03-2009
Application type:	Amendment
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)

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	EUCTR2008-002248-40-NL
CCMO	NL23590.003.08
Other	www.lillytrials.com