Duloxetine for chronic osteoarthritis pain; an important alternative?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26725

Source
NTR

Health condition

osteoarthritis; hip; knee; chronic pain; duloxetine; general practice; artrose; heup; knie; chronische pijn; huisarts

Sponsors and support

Primary sponsor: Erasmus MC
ZonMw
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Pain at 3 months measured with the WOMAC pain subscale

Secondary outcome

Pain at 1 year (WOMAC pain subscale), Disability (WOMAC function subscale)

Adverse reactions

Quality of life with the EQ-5D

Compliance to treatment (Brief Medication Questionnaire)

Patients' satisfaction

OARSI-OMERACT responder criteria

Costs; including direct medical and patient costs (iMCQ) and productivity costs (iPCQ).

Study description

Background summary

Introduction Osteoarthritis (OA) is a highly prevalent painful condition of the musculoskeletal system. The effectiveness of current analgesic options has proven to be limited and improved analgesic treatment is needed.
Several randomised placebo-controlled trials have now demonstrated the efficacy of duloxetine, an antidepressant with a centrally acting effect, in the treatment of OA pain. The aim of the current study is to investigate if duloxetine is effective and cost-effective as a third-choice analgesic added to usual care for treating chronic pain compared with usual care alone in general practice.
Methods and analysis A pragmatic open, cluster randomised trial is conducted. Patients with pain due to hip or knee OA on most days of the past 3months with insufficient benefit of non-steroidal anti-inflammatory drugs or contraindications or intolerable side effects are included. General practices are randomised to either (1) duloxetine and usual care or (2) usual care only. Primary outcome is pain at 3 months measured on the Western
Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale. Secondary outcomes at 3 months and 1 year are pain (WOMAC, at 1 year), function (WOMAC), adverse reactions, quality of life and modification of the response to treatment by the presence of centrally sensitised pain (modified PainDETECT). At 1 year, medical and productivity costs will be assessed. Analyses will be performed following the intention-to-treat principle taking the cluster design into account.
Ethics and dissemination The study is approved by the local Medical Ethics Committee (2015–293). Results will be published in a scientific peer-reviewed journal and will be communicated at conferences.
Trial registration number Dutch Trial Registry(ntr4798)

Study objective

Duloxetine is effective as third choice pain medication for treating chronic pain in osteoarthritis patients.

Study design

Baseline, 3, 6, 9 and 12 months

Intervention

Participating general practices will be randomized to either: 1) prescribe duloxetine as third choice pain medication in combination with usual care; or 2) provide usual care only (no antidepressants for pain
medication).

Contacts

Public
Erasmus MC, kamer NA1906
Postbus 2040
D. Schiphof
Rotterdam 3000 CA
The Netherlands
0031107043623
Scientific
Erasmus MC, kamer NA1906
Postbus 2040
D. Schiphof
Rotterdam 3000 CA
The Netherlands
0031107043623

Eligibility criteria

Inclusion criteria

1) having hip or knee OA based on the clinical ACR criteria, and 2) having chronic pain (most days of the last three months) in hip or knee, and 3) either: (i) a contra-indication for NSAIDs; (ii) adverse reactions of NSAIDs; or (iii) insufficient benefit of NSAIDs.

Exclusion criteria

1) on waiting list for hip/knee replacement, and 2) use of antidepressants, 3) contra-

indication of duloxetine (use of Monoamine Oxidase Inhibitors, having uncontrolled narrow-angle glaucoma, in combination with (other) central nervous system acting drugs, in combination with thioridazine, hypersensitivity to duloxetine)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2015
Enrollment:	362
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-09-2014
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	NL4655
NTR-old	NTR4798
Other	ZonMw : 80-83600-98-3143

Study results

Summary results

van den Driest JJ, Schiphof D, Luijsterburg PAJ, et al. Effectiveness and costeffectiveness of duloxetine added to usual care for patients with chronic pain due to hip or knee osteoarthritis: protocol of a pragmatic openlabel cluster randomised trial (the DUO trial). BMJ Open 2017;7:e018661. doi:10.1136/ bmjopen-2017-018661

van den Driest JJ, Schiphof D, Koffeman AR et al. No added value of duloxetine in patients with chronic pain due to hip or knee osteoarthritis: a cluster-randomized trial. Arthritis Rehumatol 2022; Jan 6. doi: 10.1002/art.42040