Duloxetine for chronic osteoarthritis pain; an important alternative?

Gepubliceerd: 18-09-2014 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26725

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC
ZonMw
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pain at 3 months measured with the WOMAC pain subscale

Toelichting onderzoek

Achtergrond van het onderzoek

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)

Doel van het onderzoek

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

Onderzoeksopzet

Baseline, 3, 6, 9 and 12 months

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2015
Aantal proefpersonen:	362
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-09-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4655
NTR-old	NTR4798
Ander register	ZonMw : 80-83600-98-3143

Resultaten

Samenvatting resultaten
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