Effectiveness and Cost-effectiveness of Transmural Collaborative care with Consultation Letter (TCCCL) and Duloxetine for major depressive disorder (MDD) and (sub)chronic pain in collaboration with primary care: A randomized placebo-controlled Multi-Centre trial. TCC:PAINDIP.

Published: 08-07-2008
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON39433

Source
ToetsingOnline

Brief title
Efficacy of Collaborative care and Duloxetine for major depressive disorder

Condition

- Mood disorders and disturbances NEC

Synonym
depression, melancholy

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Breburg Groep (Rijen)
Source(s) of monetary or material Support: Eli Lilly

Intervention

Keyword: chronic pain, Collaborative care, Duloxetine, major depressive disorder

Outcome measures

Primary outcome

Primary study parameters will be effectiveness on severity of depression

(measured by the PHQ9.

Secondary outcome

Secondary study parameters will be to establish cost effectiveness in terms of

QALY as measured by EuroQol-5 and SF-36 and costs measured by TIC-P; and to

establish improvement on pain in terms of BPI.

Study description

Background summary

Patients with depression often present themselves with pain. Pain is a symptom that occurs in up to 70% of depressed patients. The burden of pain in depression is high for patients and doctors in terms of disability, welbeing and use of medical care. However, treatment of pain in depressive patients has until yet not received much attention. Therefore, in the proposed trial, three modules for treatment of major depression with concomitant pain will be evaluated in terms of (cost)effectiveness.

Study objective

The objective of this study is to establish the (cost) effectiveness of transmural collaborative care including a Consultation Letter for the GP and duloxetine (TCCCL) versus Duloxetine in patients with depression that present themselves with (sub)chronic pain. Therefore, in this proposed pragmatic trial, such a module for treatment of concomitant (sub)chronic pain and depression will be evaluated in terms of (cost)effectiveness in a design with three treatment arms. The following three treatment options will be compared in a factorial design: TCCCL + duloxetine versus TCCCL + placebo versus duloxetine.

Study design

Randomized Placebo-controlled for the medication part double blinded multicenter trial. The following three treatment options will be compared in a factorial design: TCCCL + duloxetine versus TCCCL + placebo versus duloxetine. Intention to treat analysis will be performed.
Lead-in period: none. Design controls: double blind for medication part.

Intervention

The intervention will consist of TCCCL and/or Duloxetine.

Study burden and risks

During this study there are no risks for the patients and the patients will only derive benefit from treatment.

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

Patient type: Patients, male/female. Age range: 18 years or older. Patients that present themselves with major depressive disorder with concomitant pain symptoms of more than 6 weeks duration will be included.

Exclusion criteria

Patients with pain for which by diagnostic medical assessment a structural and continuing physical cause has been found in terms of tissue damage, illness or otherwise, that requires treatment, such as pain due to cancer or recent post traumatic pain, are excluded from the study and advised to seek such treatment. Other exclusion criteria are:
*a PHQ-9 < 10 or a BPI score < 3,
*alcohol use >3 units a day or drug abuse or dependence in the last 6 months, defined as current use of any hard drugs or cannabis
*psychotic symptoms or use of antipsychotic medication that may influence perception of pain;
*use of St John*s wort (Hypericum Perforatum),
*pregnancy and breastfeeding,
*inability to participate in case of too severe language barrier,
*dementia
*severe renal and liver dysfunction.
* uncontrolled hypertension
*Lastly, suicidal ideation is an exclusion criterion if this constitutes immediate danger and the need for crisis management according to the consulted psychiatrist. This will be measured with the suicidal ideation item of the PHQ-9. For this purpose, a suicide protocol is used in the study, defining degrees of suicide risk and prescribing necessary steps to be taken to advert such risk.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-12-2011
Enrollment:	219
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cymbalta
Generic name:	Duloxetine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	08-07-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-07-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	19-07-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2009-010188-18-NL
CCMO	NL30081.029.10