The effectiveness of antidepressants and psychological interventions in treating conversion disorder, motor type: a randomized placebo controlled clinical trial.

Published: 18-06-2009
Last updated: 06-05-2024

To examnine the effectiveness of psychological interventions and psychopharmacological interventions compared to placebo-control.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Somatic symptom and related disorders
Study type	Interventional

Summary

ID

NL-OMON33963

Source
ToetsingOnline

Brief title
Treatment of Conversion Disorder

Condition

- Somatic symptom and related disorders

Synonym
hysteria, unexplained medical symptoms

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Nijmegen (Nijmegen)
Source(s) of monetary or material Support: subsidie is verstrekt door Achmea Stichting Slachtoffer Fonds

Intervention

Keyword: antidepressants, conversion disorder, psychological interventions, treatment outcome

Outcome measures

Primary outcome

The main study parameters are improvement in intensity of conversion symptoms

as measured with the VRMC (Moene et al. 2002), the number of conversion

symptoms as measured with the SCID I and improvement on the Clinical Global

Improvement Scale.

Secondary outcome

Secundary outcome measurues will be general psychopathology measures, f.i.

depression, anxiety and physical complaints and daily life functioning.

Study description

Background summary

Conversion disorder is a psychiatric disorder which is categorized in the DSM-IV as a somatoform disorder. It is characterized by disturbances of the voluntary motor or sensory functions. Although these symptoms suggest neurological or organic causes, they lack an adequate medical explanation (American Psychiatric Association, 1994). It is a highly impairing disorder associated with high psychological and economical costs. To date there is no agreement on the most effective treatment of conversion disorder. Recently, some studies showed support for the use of antidepressants (Voon & Lang, 2005) and psychological interventions (Moene, et al., 2002; Moene et al., 2003). However, these studies suffer from several methodological impairments and randomized controlled studies comparing the effectiveness of pharmacotherapy in

the treatment of conversion disorder are still lacking. In this randomized placebo controlled study we will examine the treatment effects of psychological interventions and citalopram in patients with conversion disorder (motor type).

Study objective

To examnine the effectiveness of psychological interventions and psychopharmacological interventions compared to placebo-control.

Study design

The conducted research is a randomized placebo controlled study. Assessments are conducted pre-treatment, post treatment and at 3 and 12 months follow-up.

Intervention

Participants are randomly assigned to one of three conditions. Patients in the psychological intervention condition receive a manualized psychological treatment, which consists of 10 weekly sessions with a therapist. Participants in the antidepressant condition will receive citalopram (20-60mg) and will have a two-weekly contact with the psychiatrist. For the placebo-control condition the same protocol as the antidepressant group will be followed, only participants will receive a placebo drug. Patients in the placebo-condition will be offered effective treatment after the post treatment assessment.

Study burden and risks

The burden and risks of the current study are limited. Both the psychological treatment and treatment with antidepressants is expected to be an effective form of treatment. Compared to treatment as usual participants will invest some extra time because of the assessments. However, the amount of extra time is limited and spread over fifteen months.

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

1) Current DSM-IV disorder of Conversion Disorder motor type as established with a structured diagnostic interview (MINI)
2) Age minimum of 18 years
3) Duration of symptoms at least one month
4) Exclusive neurological examinations must have taken place (e.g. MRI, EMG, etc.) in which no neurological or other somatic explanation for the symptoms is found.

Exclusion criteria

1) A neurological disorder that can fully explain the symptoms as concluded by neurological examination (MRI, EMG, etc.)*
2) Psychosis or delusion disorder (current or in the past)
3) Suicidality
4) Mental retardation
5) Substance abuse or dependence
6) Hypersensitivity to citalopram
7)The use of citalopram currently or in the past when described in an adequate dosage to treat conversion symptoms
8)The use of another SSRI (currently)
9) Reduced hepatic or renal function
10) Pregnancy and lactation
11)The use of a drug which has known negative interaction effects with citalopram:
a) MAO inhibiters (currently or recent)

b) pimozide
12) Difficulty to understand the Dutch language.
* A concomitant neurological disorder is no exclusion criteria when symptoms are not fully explained by the condition and criteria for conversion disorder are met.

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):	11-01-2010
Enrollment:	105
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	citalopram
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	18-06-2009
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-01-2010
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	EUCTR2008-004167-19-NL
CCMO	NL23917.091.08