Dopamine/serotonin dysbalance in dystonia.

No registrations found.

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

Summary

ID

NL-OMON23462

Source
NTR

Health condition

Dystonia
Myoclonus/jerks
Psychiatric co-morbidity (e.g. depression, anxiety disorders)

Dystonie
Myoclonieen of schokken
Psychiatrische aandoeningen, zoals depressie en angsstoornissen

Sponsors and support

Primary sponsor: Academic Medical Center, University of Amsterdam
Source(s) of monetary or material Support: Self-financed
Additional funds will be requested

Intervention

Outcome measures

Primary outcome

Proportion of patients that change at least 1 point on Clinical Global Impression scale after

treatment on jerks.

Secondary outcome

1. Type of psychiatric co-morbidity in dystonia patients;

2. Number of points change on CGI scale before and after treatment on psychiatric symptoms and dystonia;

3. Number of points change on neurological and psychological scales.

Study description

Background summary

Rationale:

There are several clues that dystonia, and co-morbid myoclonus and psychiatric conditions, are caused by a dysbalanced dopaminergic and serotonergic system. In this project, we will test this hypothesis. This project will contribute to the knowledge about the pathophysiology of dystonia and may point to new therapeutic options in patients with dystonia.

Objective:

To investigate if jerks and psychiatric disorders in patients with dystonia are associated with a hyperdopaminergic/ hyposerotonergic system and whether reversal of a hyposerotonergic state has a therapeutic effect.

Study design:

This study consists of three parts: randomized, double-blind, placebo-controlled, crossover trial with escitalopram, an SSRI.

Study population:

Patients with dystonia with and without jerks.

Intervention:

Escitalopram 10 mg will be administered for 6 weeks in a randomized, placebo-controlled, double-blind, crossover trial with a washout period of 6 weeks.

Main study parameters/endpoints:

Proportion of patients that change at least 1 point on CGI scale after treatment on jerks.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients will undergo a neurological, neuropsychological and psychiatric evaluation four times. Subjects will have to take medication, escitalopram and placebo, each for 6 weeks.

They will undergo 2 venapunctions with the withdrawing of 5 mL blood. The burden of this study consists of 2 visits in 18 weeks.

The risks associated with participation in these studies are low: the psychiatric questionnaires used in our study are considered to be mildly psychologically stressful. Escitalopram is a widely used drug with little side effects. In the long term this study may lead to new treatment options for patients with dystonia.

Study objective

N/A

Study design

Subjects will be neurologically and psychiatrically evaluated 4 times during the trial (before and after each treatment round). Results of escitalopram and placebo treatment will be compared at the end of the study, when the randomization code is broken.

An interim analysis will be carried out by an independent statistician after 35 patients completed the first treatment round.

Intervention

Subjects are randomly assigned to first receive one of the following treatment regimens for a period of 6 weeks:

1. Escitalopram 10 mg tablets orally;

2. Placebo tablets orally.

After a washout period of 6 weeks the interventions will be switched: the patients who received escitalopram will receive placebo and vice versa. Because of the crossover design every patient will be his own control.

During the medication trial subjects will be neurologically and psychiatrically examined 4 times. Effects of escitalopram and placebo treatment will be compared.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 18 and 80 years old;

2. Informed consent;

3. Primary dystonia treated with botulinum toxin injections in the Academic Medical Center;

4. Stable Tsui scale for severity of dystonia for at least one year.

Exclusion criteria

1. Other neurological conditions at inclusion or in the past;

2. Use of medication or drugs with a known effect on the execution of tasks, besides anti-epileptic drugs;

3. Treatment with deep brain stimulation for dystonia;

4. SSRI use in the past 6 months prior to or during the study;

5. Use of other anti-depressants during the study, especially MAO-B inhibitors;

6. Symptomatic therapy for dystonia other than botulinum toxin;

7. Use of medication with a known effect on dopamine or serotonin receptors or transporters or with a known interaction with escitalopram;

8. Pregnancy or nursing.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2010
Enrollment:	68
Type:	Actual

Ethics review

Positive opinion

Date:	22-01-2010

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	NL2061
NTR-old	NTR2178
Other	EudraCT : 2009-018016-25
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A