Dopamine/serotonin dysbalance in dystonia.

Gepubliceerd: 22-01-2010 Laatst bijgewerkt: 18-08-2022

N/A

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

Samenvatting

ID

NL-OMON23462

Bron
NTR

Aandoening

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

Dystonie
Myoclonieen of schokken
Psychiatrische aandoeningen, zoals depressie en angsstoornissen

Ondersteuning

Primaire sponsor: Academic Medical Center, University of Amsterdam
Overige ondersteuning: Self-financed
Additional funds will be requested

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

N/A

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Postbus 22660
MAJ Koning-Tijssen, de
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663842

Wetenschappelijk

Postbus 22660
MAJ Koning-Tijssen, de
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663842

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2010
Aantal proefpersonen:	68
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	22-01-2010

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

Resultaten

Samenvatting resultaten
N/A