Botulinum toxin in the treatment of orofacial tardive dyskinesias: a single blind study.

No registrations found.

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

Summary

ID

NL-OMON24924

Source
NTR

Brief title
N/A

Health condition

N/A

Sponsors and support

Primary sponsor: Botulinum toxin A ampules by Ipsen, pharmaceutical group
Source(s) of monetary or material Support: Stichting tot Steun VCVGZ

Intervention

Outcome measures

Primary outcome

Abnormal Involuntary Movement Scale (AIMS) and the number of patients that wanted to continue the treatment with botulinum toxin after cessation of the study.

Secondary outcome

Visual Analogue Scale, World Health Organization Quality Of Life, abbreviated version.

Study description

Background summary

Tardive dyskinesias can occur as a severe side-effect after longterm treatment with neuroleptic agents. So far, there is no effective treatment for tardive dyskinesias. A few case studies and one open clinical trial suggested that botulinum toxin may be beneficial in the treatment of orofacial tardive dyskinesias. Therefore, 14 patients with orofacial tardive dyskinesias were included for participation into a study in which the effect of botulinum toxin A was investigated in a single blind session with 3 treatment sessions.

Study objective

Botulinum toxin A declines the severity of tardive dyskinisias.

Study design

N/A

Intervention

4 injections of 10mu botulinum toxin A in the orbicularis oris muscle in 3 sessions (1 per 3 months). The dosage could be increased to 15 or 20mu per injection site, depending on effect and/or side-effects.

Contacts

Public
Stadhoudersplantsoen 2
C.W. Slotema
Stadhoudersplantsoen 2
Den Haag 2517 JL
The Netherlands
+31 (0)70 3918600
Scientific
Stadhoudersplantsoen 2
C.W. Slotema

Stadhoudersplantsoen 2
Den Haag 2517 JL
The Netherlands
+31 (0)70 3918600

Eligibility criteria

Inclusion criteria

Patients suffering from orofacial tardive dyskinisias for at least 3 months, stable dosage of psychopharmacological medication and written informed consent by the patient.

Exclusion criteria

Age younger than 18 years, contraindication for botulinum toxin (myasthenia gravis, Lambert Eaton Myasthenic Syndrome) and women known to be pregnant or having a positive pregnancy test.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2004
Enrollment:	14
Type:	Actual

Ethics review

Positive opinion

Date:	08-12-2005
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	NL532
NTR-old	NTR576
Other	: N/A
ISRCTN	ISRCTN81508784

Study results

Summary results

Prog Neuropsychopharmacol Biol Psychiatry. 2008 Feb 15;32(2):507-9. Epub 2007 Oct 13.