

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

Submission date 08/03/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/03/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/08/2009	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR576

Study information

Scientific Title

Study objectives
Botulinum toxin A decreases the severity of tardive dyskinesias.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Single blind uncontrolled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Tardive dyskinesia

Interventions

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

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s))

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

Completion date

31/10/2004

Eligibility**Key inclusion criteria**

1. Patients suffering from orofacial tardive dyskinesias for at least 3 months
2. Stable dosage of psychopharmacological medication
3. Written informed consent by the patient

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Age younger than 18 years
2. Contraindication for botulinum toxin (myasthenia gravis, Lambert Eaton Myasthenic Syndrome)
3. Women known to be pregnant or having a positive pregnancy test

Date of first enrolment

01/02/2004

Date of final enrolment

31/10/2004

Locations**Countries of recruitment**

Netherlands

Study participating centre

Stadhoudersplantsoen 2

The Hague

Netherlands

2517 JL

Sponsor information**Organisation**

Parnassia Psycho-medical Centre (Netherlands)

ROR

<https://ror.org/002wh3v03>

Funder(s)

Funder type

Charity

Funder Name

Support Foundation of the Christian Association for the Care of Nervous Disorders (Stichting tot Steun Vereniging tot Christelijke Verzorging van Geestes en Zenuwzieken [VCVGZ]) (Netherlands)

Funder Name

Ipsen pharmaceutical group (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/02/2008		Yes	No