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

Submission date 08/03/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/03/2006	**Overall study status** Completed	
Last Edited 19/08/2009	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Other

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures

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

Overall study start date
01/02/2004

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

Age group
Adult

Sex
Both

Target number of participants
14

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)

Sponsor details
Mangostraat 15
The Hague
Netherlands
2552 KS

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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