Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Therapeutic effectiveness of local Botulinum toxin injection on hand tremor severity and upper limb function in patients with Parkinson disease_ a randomized clinical trial

Protocol summary

Study aim

Therapeutic effectiveness of local Botulinum toxin injection on hand tremor severity and upper limb function in patients with Parkinson disease

Design

Randomized clinical trial without blindness phase 4. In this study, 35 patients with Parkinson's disease and hand tremor are selected, randomly assigned to two different treatment groups.

Settings and conduct

The target population is people with Parkinson's disease that suffer from hand tremor and are referred to the specialized clinics of Physical Medicine and Neurology affiliated with Tabriz University of Medical Sciences. Sampling is done by convenience non-randomized method. To conceal the allocation, the same envelope is used in the opaque package to be numbered sequentially.

Participants/Inclusion and exclusion criteria

Entry criteria: people with Parkinson's disease (PD) aged 30-85 years who pasted one year of its definite diagnosis with hand tremor, stages I-III, consuming routine anti-Parkinson's drugs especially levodopa, desire to participate in the study and satisfaction with Botulinum toxin injections; Exit criteria: cognitive impairment or psychosis, history of toxin injection of botulinum or any other injection over the past four months, history of DBS surgery, secondary Parkinsonism such as pharmaceutical Parkinsonism and anti-psychotics drugs, pregnancy and breastfeeding

Intervention groups

The target group are randomly assigned to two different treatment groups: 25 patients in the case group (diluted botulinum toxin injection in addition to oral drug therapy) and 10 patients in the control group (only receiving oral medication).

Main outcome variables

Clinical severity of hand tremor؛ Functional intensity of hand tremor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003217N11**
Registration date: **2019-02-03, 1397/11/14**
Registration timing: **prospective**

Last update: **2019-02-03, 1397/11/14**
Update count: **0**

Registration date

2019-02-03, 1397/11/14

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-19, 1397/11/30

Expected recruitment end date

2019-09-06, 1398/06/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Therapeutic effectiveness of local Botulinum toxin injection on hand tremor severity and upper limb function in patients with Parkinson disease_ a randomized clinical trial

Public title
The Effect of Local Injection of Botulinum Toxin in Parkinson's Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with idiopathic or familial Parkinson's disease (Parkinson's disease or PD); age between 30 to 85 years, one year after definitive diagnosis; patients with PD who have hand tremor (single-sided or bilateral). Patients with PD who are in stages I-III of Hoehn & Yahr staging . Patients with PD who are being treated with routine anti-Parkinson drugs, especially levodopa. Patients with PD who are willing to participate in the study and are satisfied with botulinum toxin injections.
Exclusion criteria:
Patients with PD who have had cognitive impairment or psychosis Patients with PD who have had a history of botulinum Toxin injection or any other injection over the past four months Patients with PD who have had a history of surgery (DBS: deep brain stimulation) Patients with secondary Parkinsonism, such as Pharmaceutical Parkinsonism Patients with hand tremor which is resulting from a medical condition, such as antipsychotic drugs Pregnancy and breastfeeding
Age
From **30 years** old to **85 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **35**
Randomization (investigator's opinion)
Randomized
Randomization description
A box containing 35 concealed envelopes is selected. In the 25 envelopes paper for group A and inside the other 10 envelopes, paper for group B is placed. This box is located in front of the patients and an envelope is chosen by each patient. Thus, the patient is completely unaware of group typing and randomly assigned to group A (case) or group B (control). The patient's name is recorded in the list of 25 patients in the case group or 10 patients in the control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Regional Ethics Committee of Tabriz University of Medical Sciences
Street address
Vice Chancellor for Research, Tabriz University of Medical Sciences, Golghasht St.
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Province
East Azarbaijan
Postal code
5166614756
Approval date
2018-11-14, 1397/08/23
Ethics committee reference number
IR.TBZMED.REC.1397.657

Health conditions studied

1

Description of health condition studied
Parkinson's Disease
ICD-10 code
G20
ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Clinical severity of hand tremor
Timepoint
At the beginning of the study and before the intervention, 1.5 months, 4 months after injection
Method of measurement
2 questionnaires including FTM (Fahn_Tolosa_Marin Temor Rating Scale) and UPDRS (Unified Parkinsone Disease Rating Scale)

Secondary outcomes

1

Description
Functional severity of hand tremor
Timepoint
At the beginning of the study and before the intervention, 1.5 months, 4 months after injection
Method of measurement
ADL questionnaire from Bain and Findley questionnaire, manual dynamometer, 10 euro coin test

Intervention groups

1

Description
Intervention group: injection of diluted Botulinum toxin in the affected hand muscles in addition to Parkinson's routine oral medicine.According to studies conducted so far, 7 muscles from 14 common muscles have been injected in more than 80% of patients, including Flexor Carpi Radialis (FCR), Flexor Carpi Ulnaris (FCU), Pronator Tres, Pronator Quadratous, Extensor Caripi Radialis Longus (ECRL) and Extensor Carpi Ulnaris (ECU) and Supinator. The injectable dose is selected for each muscle depending on the moderate and standard deviation of previous successful efforts (15 ± 5 units of botulinum toxin). According to available resources and general consensus and prevention of severe weakness, to each specified muscles of the forearm flexor, 20 units of Botulinum toxin are injected and to each prescribed muscles of the forearm extensor should be injected 10 to 15 units of Botulinum toxin.
Category
Treatment - Drugs

2

Description
Control group: 10 people in the control group received only Parkinson’s routine oral medication
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Fariba Eslamiyan
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Leila Fallah
Position
Physical Medicine and Rehabilitation resident
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available