Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A clinical trial: comparative effectiveness of oral propranolol and Dysport injection on tremor severity in essential hand tremor

Protocol summary

Summary

The purpose of this study is comparison of Dysport (abobotulinumA) injection with oral propranolol outcomes in treatment of essential hand tremor. Seventy eight patients coming to Dr Asadi's clinic in Imam Reza hospital or his office with moderate to severe essential hand tremor will be enrolled. Their tremor should not be due to other diseases or drugs and they should not have Dysport or propranolol contraindications. After taking an informed consent, they will be divided into two groups randomly by tossing. Group A (n=30) will receive a Dysport injection in forearm muscles. For group B (n=48) will be prescribed oral propranolol for 3 months. Before intervention, tremor severity will be assessed using tremor research group essential tremor rating assessment scale (TETRAS) and the short form 36 (SF-36) quality of life questionnaire will be answered by patients. Furthermore after 1, 2, 3 months, tremor severity will be assessed again and after 2 months, the second questionnaire will be answered. Finally the results will be analyzed. Evaluating researcher will not be informed about intervention type (single blinded). There is no placebo control group because of ethics considerations.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607022415N2**
Registration date: **2016-08-22, 1395/06/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-22, 1395/06/01

Registrant information

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Bahador Asadi Khansari
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Recruitment status

Recruitment complete

Funding source

Army university of medical sciences

Expected recruitment start date

2016-08-05, 1395/05/15

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial: comparative effectiveness of oral propranolol and Dysport injection on tremor severity in essential hand tremor

Public title

Treatment of essential hand tremor: Dysport versus propranolol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: essential hand tremor with severity equal or greater than 2 according to tremor research group essential tremor rating assessment scale (TETRAS)

version 3.1 (paragraph 4); normal thyroid function test; age higher than 18 years; exclusion criteria: drug induced tremor; pregnancy and lactation; allergy to cow milk protein; propranolol contraindications for example heart block, congestive heart failure, diabetes melitus, asthma and etc; history of botulinum injection in upper limb; recent botulinum injection in any part of body since 8 months ago; allergy to botulinum; history of myasthenia gravis or suspicious to myasthenia gravis; parkinson disease; use of anti-dopaminergic medications

Age
From **18 years** old to **100 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of army university of medical sciences

Street address
ethics committee, army university of medical sciences, Etemadzade st, Fatemi st

City
Tehran

Postal code

Approval date
2016-08-01, 1395/05/11

Ethics committee reference number
18/9175/الف/ج

Health conditions studied

1

Description of health condition studied
essential hand tremor

ICD-10 code
G25.0

ICD-10 code description
Essential tremor

Primary outcomes

1

Description
hand tremor severity

Timepoint
before treatment, one and two and three months following the start of treatment

Method of measurement
tremor research group essential tremor rating assessment scale (TETRAS)

2

Description
quality of life

Timepoint
before treatment, two months following start of treatment

Method of measurement
short form 36 (SF-36) quality of life questionnaire

Secondary outcomes

1

Description
side effects

Timepoint
one and two and three months following start of treatment

Method of measurement
history taking

Intervention groups

1

Description
Dysport intramuscular injection in forearm 100-150 unit once

Category
Treatment - Drugs

2

Description
tablet propranolol 40-160 mg daily for 3 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Dr Asadi
Street address
third floor, Imam Reza hospital, Etemadzadeh street, Fatemi street
City
Tehran

2

Recruitment center
Name of recruitment center
Dr Bahador Asadi's office
Full name of responsible person
Mrs Kalimi
Street address
unit 9, third floor, No 24, alley 21, south Gandhi street
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, army university of medical Sciences
Full name of responsible person
Dr Kamran Azma
Street address
Vice chancellor for research, Army university of medical sciences, Etemadzadeh street, Fatemi street
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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
Vice chancellor for research, army university of medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty