

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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

Name

Bahador Asadi Khansari

Name of organization / entity

Army University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 2277 1487

Email address

peiman_asadi@ajaums.ac.ir

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/ح

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

Tehran

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

City

Tehran

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

Army university of medical sciences

Full name of responsible person

Saeed Amiri

Position

researcher/MD

Other areas of specialty/work**Street address**

Elites office, army university of medical sciences,
Etemadzadeh street, Fatemi street

City

Tehran

Postal code**Phone**

+98 21 8833 7920

Fax**Email**

dr.saeed.amiri@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Army university of medical sciences

Full name of responsible person

Dr Bahador Asadi

Position

Neurologist/assistant professor

Other areas of specialty/work**Street address**

third floor, Imam Reza hospital, Etemadzadeh street,
Fatemi street

City

Tehran

Postal code**Phone**

+98 21 8802 8350

Fax**Email**

peimanasadi1353@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Army university of medical sciences

Full name of responsible person

Saeed Amiri

Position

researcher/MD

Other areas of specialty/work**Street address**

Elites office, army university of medical sciences,
Etemadzadeh street, Fatemi street

City

Tehran

Postal code**Phone**

+98 21 8833 7920

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