# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparison of the efficacy of intra-muscular Botulinum toxin type A with oral Tizanidine in the treatment of upper limb spasticity and functional improvement due to cerebral stroke.

## Protocol summary

**Summary**

Our aim in this study is comparison of the Botulinum toxin type A with oral Tizanidine in the treatment of spasticity due to stroke. The key inclusion criteria was to have a history of cerebral stroke for at least 3 months ago and the key exclusion criteria was to have a systemic disorder. In a randomized unicentral single blinded study 68 patients from both genders with upper limb spasticity referring to the neurology clinic of Emam Reza hospital, Tabriz, Iran, were assigned in two equally-sized groups to receive oral Tizanidine or intra-muscular Botulinum toxin. For the first group, Tizanidine will be started with 2 mg/day and added 2 mg/week until the dose of 16 mg/day in week 16. Patients will be assessed in week 16. In Botulinum group, patients will be injected two doses of Botulinum into the upper limb muscles with a 3-4 month time gap. Limb spasticity in Ashworth scale and Limb function improvement in ARAT scale in the start of the study for all the patients, week 16 (for Tizanidine) and 3 months after the last injection (for Botulinum) will be measured and the results will be compared within and between the groups.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2012112411563N1**
Registration date: **2012-12-06, 1391/09/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2012-12-06, 1391/09/16

**Registrant information**

**Name**

Mohammad Yazdchi

**Name of organization / entity**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Tabriz University of Medical Sciences

**Expected recruitment start date**

2012-04-04, 1391/01/16

**Expected recruitment end date**

2012-12-06, 1391/09/16

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the efficacy of intra-muscular Botulinum toxin type A with oral Tizanidine in the treatment of upper limb spasticity and functional improvement due to cerebral stroke.

**Public title**

Comparison of the Botulinum toxin type A with oral Tizanidine in the treatment of spasticity due to stroke

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: (to have a history of cerebral stroke for

at least 3 months ago; severity of spasticity more than 2 in Ashworth scale; to be older than 35 years old)
Exclusion criteria: (patients with impairment in level or content of consciousness; to have systemic disorders such as Diabetes, hyperthyroidism, electrolyte disorders, renal failure; to be older than 70 years old)

**Age**
From **35 years** old to **70 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **68**

**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 Tabriz University of Medical Sciences

**Street address**
Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Square

**City**
Tabriz

**Postal code**

**Approval date**
2012-04-03, 1391/01/15

**Ethics committee reference number**
9122

## Health conditions studied

### 1

**Description of health condition studied**
Spasticity due to cerebral stroke

**ICD-10 code**
I69.3

**ICD-10 code description**
Sequelae of cerebral infarction

## Primary outcomes

### 1

**Description**
Limbs Spasticity

**Timepoint**
in the start of the study for all the patients, week 16 (for Tizanidine) and 3 months after the last injection (for Botulinum)

**Method of measurement**
Based on Ashworth scale

### 2

**Description**
Limb functional improvement

**Timepoint**
in the start of the study for all the patients, week 16 (for Tizanidine) and 3 months after the last injection (for Botulinum)

**Method of measurement**
Based on ARAT scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
For Tizanidine group: Tizanidine will be started with 2 mg/day orally and added 2 mg/week until the dose of 16 mg/day in week 16.

**Category**
Treatment - Drugs

### 2

**Description**
In Botulinum group, patients will be injected two doses of Botulinum (not more than 1000 units/dose) into the upper limb muscles with a 3-4 month time gap.

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Neurology clinic of Emam Reza hospital

**Full name of responsible person**
Mohammad Yazdchi

**Street address**

**City**
Tabriz

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Tabriz University of Medical Sciences
**Full name of responsible person**
Alireza Ostad Rahimi
**Street address**
Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square
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Tabriz
**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**
*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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*