

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The safety and efficacy of intradermal injection of type A botulinum toxin in chemotherapy induced peripheral neuropathy

#### Protocol summary

##### Study aim

Evaluation the safety and efficacy of intradermal injection of botulinum toxin type A on chemotherapy induced peripheral neuropathy

##### Design

Patients with chemotherapy induced peripheral neuropathy received 150 units of botulinum toxin type A in 2 ml normal saline 0.9% intradermally. The injections were performed in the palmar side and tips of fingers of one of the hands and the other was considered as the control (no injection). The injections were performed by insulin syringe at 10 points of the palm and fingers and the patients were followed for 8 weeks after. NPS and VAS index were used to compare treatment and control groups.

##### Settings and conduct

Patients oncology clinic with chemotherapy induced neuropathy at imam hosein hospital were referred to the pain clinic of the same hospital

##### Participants/Inclusion and exclusion criteria

Chemotherapy induced neuropathy due to taxans or platinums and grade 2 or more of neuropathy and ages between 18 to 69 and a good cooperation. exclusion criterias Lack of cooperation/ history of neuropathy before chemotherapy/ history of allergy to botulinum toxin/local infection at the site of injections/ radiculopathy/ known renal disease/ alcohol or substance abuse/ history of miastenia gravis/ use of aminoglycosides History of taking palliative medications for neuropathy during last month

##### Intervention groups

Injection of 150 units of botulinum toxin type A in 2 ml normal saline 0.9% intradermally in one hand and the other hand as a control and without an intervention

##### Main outcome variables

Pain measurement based on neuropathic pain scale (NPS ) and visual analogue scale (VAS)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200425047202N1**

Registration date: **2020-07-07, 1399/04/17**

Registration timing: **retrospective**

Last update: **2020-07-07, 1399/04/17**

Update count: **0**

##### Registration date

2020-07-07, 1399/04/17

##### Registrant information

##### Name

Atefeh Tutunchi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4464 8904

##### Email address

tutunchi.md@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-23, 1398/06/01

##### Expected recruitment end date

2020-02-20, 1398/12/01

##### Actual recruitment start date

2019-08-23, 1398/06/01

##### Actual recruitment end date

2020-02-20, 1398/12/01

##### Trial completion date

2020-04-19, 1399/01/31

##### Scientific title

The safety and efficacy of intradermal injection of type A botulinum toxin in chemotherapy induced peripheral neuropathy

#### Public title

The safety and efficacy of intradermal injection of type A botulinum toxin in chemotherapy induced peripheral neuropathy

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Chemotherapy induced neuropathy in patients treated with taxans or platinum with grade 2 or more of neuropathy

##### Exclusion criteria:

Lack of cooperation//////// History of neuropathy before chemotherapy History of allergy to the botulinum toxin Local infection of the injection places Radiculopathy History of mental disease Alcohol or substance abuse Known renal disease History of myasthenia gravis Use of aminoglycosides

#### Age

From **18 years** old to **69 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

one hand as a case and the other as a control

Actual sample size reached: **30**

More than 1 sample in each individual

Actual sample size in each individual: **2**

one hand as a case and the other as a control

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### 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

Shahid beheshti university of medical sciences

#### Street address

Apadana complex

#### City

Tehran

#### Province

Tehran

#### Postal code

1391875461

#### Approval date

2018-07-25, 1397/05/03

#### Ethics committee reference number

IR.SBMU.MSP.REC.1397.412

### Health conditions studied

#### 1

##### Description of health condition studied

Chemotherapy induced neuropathy

##### ICD-10 code

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

Pain reduction in control arm

##### Timepoint

before and then 4 and 6 and 8 weeks after the intervention

##### Method of measurement

VAS and NPS questionnaire

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

injection of 150 units of botulinum toxin type A in 2 ml normal saline at 10 points of palmar side of one hand intradermally

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: no injections

##### Category

N/A

### Recruitment centers

#### 1

##### Recruitment center

Name of recruitment center

Imam hosein hospital  
**Full name of responsible person**  
Atefeh Tutunchi  
**Street address**  
Shahid madani  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1617763141  
**Phone**  
+98 21 7343 3000  
**Email**  
info@ehmc.ir  
**Web page address**

**Full name of responsible person**  
Atefeh Tutunchi  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Radiotherapy  
**Street address**  
Apadana complex  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1391875461  
**Phone**  
+98 21 4464 8904  
**Email**  
tutunchi.md@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Afshin Zarghi  
**Street address**  
Yaman  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1985717443  
**Phone**  
+98 21 23871  
**Email**  
info@sbmu.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Beheshti 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**  
Shahid Beheshti University of Medical Sciences

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Atefeh Tutunchi  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Radiotherapy  
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tutunchi.md@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Atefeh Tutunchi  
**Position**  
Resident  
**Latest degree**  
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**Province**

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**Postal code**

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**Phone**

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**Email**

tutunchi.md@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Questionnaires will be available

**When the data will become available and for how long**

At the end of the study

**To whom data/document is available**

Every one

**Under which criteria data/document could be used**

It would be available for researches with mentioning the name

**From where data/document is obtainable**

tutunchi.md@gmail.com

**What processes are involved for a request to access data/document**

through the email

**Comments**