Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The saftey and efficacy of intradermal injection of type A butulinum 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 referd 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 butulinum 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
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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 saftey and efficacy of intradermal injection of type A butulinum toxin in chemotherapy induced peripheral neuropathy

Public title
The saftey and efficacy of intradermal injection of type A butulinum toxin in chemotherapy induced peripheral neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Chemotherapy induced neuropathy in patients treated with taxans or platinums with grade 2 or more of neuropathy
Exclusion criteria:
Lack of cooperation/////// History of neuropathy before chemotherapy History of allergy to the butulinum toxin Local infection of the injection places Rradiculopathy History of mental disease Alcolol or substance abuse Known renal disease History of miastenia 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 scinces
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 butulinum 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
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Postal code
1617763141
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Email
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Web page address

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
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Province
Tehran
Postal code
1985717443
Phone
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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
Full name of responsible person
Atefeh Tutunchi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
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Person responsible for updating data

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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