

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Effect of botulinum toxin A injection versus no intervention on clinical sign in women with facial flushing: a before after clinical trial

#### Protocol summary

##### Summary

**Objectives:** To assess the effect of botulinum toxin A injection versus no intervention on clinical sign in women with facial flushing **Design:** a before after clinical trial. **Setting and conduct:** The eligible women facial flushing who will refer to dermatology clinic of Farshchian Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** (a) facial flushing; (b) female sex. **Exclusion criteria:** (a) carcinoid syndrome or thyroid medullary cell carcinoma; (b) pregnancy or breast feeding; (c) systemic diseases. **Intervention:** A single dose intradermal injection of 2 IU botulinum toxin A (Neuronox) in every 1 cm in each chin to a maximum of 30 IU. **Control:** Compared to before intervention. **Primary outcome:** Clinical sign of flashing before and one month after intervention using DLQI questionnaire. **Secondary outcome:** (a) unintended facial paralysis or partial paralysis of lower eyelid one month after intervention through history taking; (b) strabismus one month after intervention through history taking.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201503129014N59**  
Registration date: **2015-04-25, 1394/02/05**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-04-25, 1394/02/05

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

##### Expected recruitment start date

2015-03-21, 1394/01/01

##### Expected recruitment end date

2016-12-20, 1395/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of botulinum toxin A injection versus no intervention on clinical sign in women with facial flushing: a before after clinical trial

##### Public title

Effect of botulinum toxin A injection versus no intervention on clinical sign in women with facial flushing

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:** (a) facial flushing; (b) female sex. **Exclusion criteria:** (a) carcinoid syndrome or thyroid medullary cell carcinoma; (b) pregnancy or breast feeding; (c) systemic diseases.

##### Age

No age limit

**Gender**

Female

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: 22

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features**

Randomization: This is a before after trial therefore randomization is impossible. Blinding: Blinding is impossible.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethic Committee of Hamadan University of Medical Sciences

**Street address**

Vice-chancellor of Research the Technology,  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave Hamadan

**City**

Hamadan

**Postal code**

6517838695

**Approval date**

2015-04-11, 1394/01/22

**Ethics committee reference number**

P/16/35/9/6

**Health conditions studied****1****Description of health condition studied**

Flushing

**ICD-10 code**

R23.2

**ICD-10 code description**

Flushing

**Primary outcomes****1****Description**

Clinical sign of flashing

**Timepoint**

before and one month after intervention

**Method of measurement**

using DLQI questionnaire

**Secondary outcomes****1****Description**

unintended facial paralysis or partial paralysis of lower eyelid

**Timepoint**

one month after intervention

**Method of measurement**

through history taking

**2****Description**

strabismus

**Timepoint**

one month after intervention

**Method of measurement**

through history taking

**Intervention groups****1****Description**

A single dose intradermal injection of 2 IU botulinum toxin A (Neuronox) in every 1 cm in each chin to a maximum of 30 IU

**Category**

Treatment - Drugs

**2****Description**

Compared to before intervention

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Farshchian Hospital

**Full name of responsible person**

Dr Gholamreza Eshghi

**Street address**

Farshchian Hospital, Mirzadeh Eshghi Ave.

**City**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**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 the Technology, Hamadan  
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**

Farshchian Hospital

**Full name of responsible person**

Dr Leila Khezrian

**Position**

Resident of Dermatology

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## Person responsible for scientific

## inquiries

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## Person responsible for updating data

**Contact****Name of organization / entity**

Department of Epidemiology & Biostatistics

**Full name of responsible person**

Dr Jalal Poorolajal

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Associate Professor of Epidemiology

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Public Health, Hamadan University of Medical  
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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*