

# 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

poorolajal@umsha.ac.ir

##### 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

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

Farshchian Hospital, Mirzadeh Eshghi Ave.

**City**

Hamadan

**Postal code****Phone**

+98 81 3827 4184

**Fax****Email**

khezrian.leila@yahoo.com

**Web page address**

## Person responsible for scientific

## inquiries

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

Farshchian Hospital

**Full name of responsible person**

Dr Gholamreza Eshghi

**Position**

Dermatologist

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

Farshchian Hospital, Mirzadeh Eshghi Ave.

**City**

Hamadan

**Postal code****Phone**

+98 81 3827 4184

**Fax****Email**

gholamrezaeshghi58@gmail.com

**Web page address**

## Person responsible for updating data

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

Department of Epidemiology & Biostatistics

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor of Epidemiology

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

Department of Epidemiology & Biostatistics, School of  
Public Health, Hamadan University of Medical  
Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Fax****Email**

poorolajal@umsha.ac.ir

**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*