

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### changing facial emotion recognition before and after cosmetic botulinum toxin type A injection

#### Protocol summary

##### Study aim

compression of changing facial emotion recognition before and after of botulinum toxin type A injection in facial muscle of patients who came for cosmetic aims with multi modal emotion recognition test (MERT)

##### Design

A non-randomized before after clinical trial of 68 patients, enrolled in February 2018, and followed for two months

##### Settings and conduct

patients who come to dermatological clinics of kerman university of medical sciences and health services

##### Participants/Inclusion and exclusion criteria

patients above 18 years old with frown lines in forehead area who come for first time of injection of botulinum toxin type A are include and pregnant women, allergy to drug, history of trauma or recent surgery in forehead area, presence of dementia or psychiatric problems and visual or speech abnormalities are exclude from the study

##### Intervention groups

eligible patients who come to cosmetic clinic for the first time of botulinum toxin injection are evaluate with MERT test before starting the study; then 8 weeks after completion of treatment, the change of emotion recognition's are evaluate.

##### Main outcome variables

evaluation and assessment of changing in emotion recognition before and after of botulinum toxin injection with MERT test

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150410021677N3**

Registration date: **2018-02-06, 1396/11/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-06, 1396/11/17**

Update count: **0**

##### Registration date

2018-02-06, 1396/11/17

##### Registrant information

###### Name

Kaveh Shafiei

###### Name of organization / entity

Kerman University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3211 5785

###### Email address

k\_shafiei@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-05, 1396/11/16

##### Expected recruitment end date

2018-04-19, 1397/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

changing facial emotion recognition before and after cosmetic botulinum toxin type A injection

##### Public title

Efficacy of Botulinum Toxin in Facial Emotion Recognition

##### Purpose

Basic science

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

first time of botulinum toxin injection age above 18 years  
presence of frown lines in forehead

**Exclusion criteria:**

allergy to botulinum toxin pregnancy history of facial  
trauma history of surgery in forehead area of face history  
of dementia and psychiatric disorder visual and speech  
abnormalities

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **68**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Kerman university of medical  
Sciences

**Street address**

Kosar square, shafa hospital

**City**

Kerman

**Province**

Kerman

**Postal code**

7618751151

**Approval date**

2018-01-17, 1396/10/27

**Ethics committee reference number**

IR.KMU.REC.1396.208296000763

**Health conditions studied**

1

**Description of health condition studied**

Disorder of the skin and subcutaneous tissue,  
unspecified

**ICD-10 code**

L98.9

**ICD-10 code description**

Disorder of the skin and subcutaneous tissue,  
unspecified

**Primary outcomes**

1

**Description**

incidence frown line in forehead

**Timepoint**

before intervention and 2 weeks after injection botulinum

**Method of measurement**

visual evaluation

**Secondary outcomes**

1

**Description**

evaluation of emotion recognition

**Timepoint**

before intervention, 8 after intervention

**Method of measurement**

multi modal emotion recognition test (MERT)

**Intervention groups**

1

**Description**

Intervention group:patients with frown lines in forehead  
area. 500 unit of botulinum toxin type  
A(Dysport,Epsen,UK)dissolve in 0.9%injectable NACL  
solution and inject 20Unit to the procerus muscle,35 U  
bilaterally to the corrugator muscles and 15U in lateral  
sentiment of orbicularis oculi.The MERT score calculate  
before and 8 week after injection.MERT test of the Swiss  
centre for affective science at the university of  
Geneva,during 45 minutes,test participanta asked to  
choose the emotion presented by actors in different  
modalities(still picture,video only,audio only and audio-  
visual),At the end of calculate the score.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Dermatological Clinic of Kerman University of medical  
sciences

**Full name of responsible person**

Kaveh Shafiei

**Street address**

kosar square.,shafa hospital

**City**

kerman  
**Province**  
Kerman  
**Postal code**  
7618751151  
**Phone**  
+98 34 3212 4727  
**Email**  
amirsherafat@mail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Kaveh shafiei  
**Street address**  
Kosar square., shafa hospital  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7618751151  
**Phone**  
+98 34 3212 4727  
**Email**  
amirsherafat@mail.com

#### Grant name

Kerman university of medical sciences

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kerman 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**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Kaveh shafiei  
**Position**  
Assistant professor  
**Latest degree**  
Specialist

#### Other areas of specialty/work

Neurology

#### Street address

Kosar square., shafa hospital

#### City

Kerman

#### Province

Kerman

#### Postal code

768751151

#### Phone

+98 34 3212 4727

#### Email

amirsherafat@mail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Kaveh shafiei  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Neurology  
**Street address**  
Kosar square., shafa hospital  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
768751151  
**Phone**  
+98 34 3212 4727  
**Email**  
amirsherafat@mail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Kaveh shafiei  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Neurology  
**Street address**  
Kosar square., shafa hospital  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**

768751151

**Phone**

+98 34 3212 4727

**Email**

amirsherafat@mail.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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

All collected deidentified of IPD

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

Starting 6 month after publication

**To whom data/document is available**

Only available for people working in academic institutions

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

Only for scientific research

**From where data/document is obtainable**

Doctor Amir sherafat, neurology resident of kerman university of medical sciences, amirsherafat@mail.com,  
Doctor Kaveh shafiee, neurology assistant professor of kerman university medical sciences. kshafiee@gmail.com,

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

Documents will be send 2weeks after direct request by email to the corresponding author

**Comments**

no further comments