

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Sep 2021

### The evaluation of efficacy and adverse effects of subcision in the correction of nasolabial fold

#### Protocol summary

##### Summary

The aim of current study is evaluation of the efficacy and safety of the subcision in the treatment of nasolabial folds. Participants are 10 patients between 30-60 years old with deep nasolabial folds that may cause problem for them cosmetically. Those with coagulative disorder or connective tissue disease and patients who have the history of filler injection during these five years will not allow participating in our study. The subcision needle will used in order to correct the nasolabial folds with the aim of inducing thrombosis in the nasolabial fold area that will filled the fold .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201108097270N1**  
Registration date: **2012-01-27, 1390/11/07**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-01-27, 1390/11/07

##### Registrant information

###### Name

Reza Mahmoud Robati

###### Name of organization / entity

Skin research center, Shohad-e-Tajrish hospital

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2274 1507

###### Email address

robati@razi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

##### Funding source

Skin research center, Shohada-e-Tajrish hospital,  
Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2012-02-01, 1390/11/12

##### Expected recruitment end date

2012-10-01, 1391/07/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The evaluation of efficacy and adverse effects of subcision in the correction of nasolabial fold

##### Public title

New way to treating the smile lines

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1. age 30-60y; 2.deep nasolabial fold.  
Exclusion criteria:1.age under 30y; 2.lactation & pregnancy; 3.history of coagulopathy or use of anticouagulant drug; 4.active infection in facial zone; 5.inability to stay in the study; 6.history of collagen or elastin disorder and connective tissue disease; 7.history of facial skin cancer; 8.history of topical medication administration during 1 month before study except sunscreen; 9.history of cosmetic procedure during last year (laser,...); 10. history of filler injection in nasolabial fold during last 5 years.

##### Age

From **30 years** old to **60 years** old

##### Gender

Both

#### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 10

### 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

Skin research center ethics committee, Shahid Beheshti University of Medical Sciences

##### Street address

Shohada-e-Tajrish hospital, Shahid Beheshti University of Medical Sciences

##### City

Tehran

##### Postal code

##### Approval date

2011-10-16, 1390/07/24

##### Ethics committee reference number

519/90

## Health conditions studied

### 1

#### Description of health condition studied

improvement of nasolabial fold by subcision

#### ICD-10 code

Z41.9

#### ICD-10 code description

Procedure for purposes other than remedying health state, unspecified

## Primary outcomes

### 1

#### Description

nasolabial fold

#### Timepoint

before treatment, 1 w, 1 m and 6 m after treatment

#### Method of measurement

photograph, reviscometer

## Secondary outcomes

### 1

#### Description

bleeding

#### Timepoint

immediately after treatment and the day after

#### Method of measurement

observation

### 2

#### Description

ecchymosis

#### Timepoint

2 hours, 1 day and 1 week after treatment

#### Method of measurement

observation

### 3

#### Description

infection

#### Timepoint

1 w after treatment

#### Method of measurement

physical exam

## Intervention groups

### 1

#### Description

At first, the desired area is marked and local anesthesia is undergone using lidocain 1%. The subcision needle penetrates the skin from the margin of the nasolabial fold while its sharp edge is upward. The needle will be rotated till its tip become parallel to the dermoepidermal junction. The necessary movement will be done for releasing the fibrotic band.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shohada-e-Tajrish hospital

##### Full name of responsible person

Dr. Reza Robati

##### Street address

##### City

Tehran

## Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**

Skin research center, Shohada-e-Tajrish hospital

**Full name of responsible person**

Dr. Parviz Toosi

**Street address**

Shohada-eTajrish hospital, Shahrdari St.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Skin research center, Shohada-e-Tajrish hospital

**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**

Skin Research Center, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Reza Mahmoud Robati

**Position**

associate professor/M.D

**Other areas of specialty/work**

**Street address**

Skin Research Center, Shohada-e-Tajrish hospital, Shahid Beheshti University of Medical Sciences

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robati@razi.tums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Skin Research Center, Shahid Beheshti University of Medical Sciences

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rezarobati@sbmu.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**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*