

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

Email

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Web page address

Person responsible for scientific 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

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Person responsible for general inquiries

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Name of organization / entity

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Full name of responsible person

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Street address

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Phone

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Fax

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