Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The evaluation of efficacy and adverse effects of subsicion with blunt subcision blade in the correction of nasolabial fold depth

Protocol summary

Summary

With the aim of determining the efficacy and side effects of sub-cirrhosis by Blunt Subcision Blade in the treatment of nasolabial China, 10 volunteers with deep nasolabial fibrils, after obtaining enough information and obtaining written and informed consent, are willing to enter the study. They are studying with China's criteria for the deep-seated double-sided nasolabial syndrome of over 18 years of age. Patient with raccoon over the past 12 months, the presence of active skin infection in the face, lidocaine susceptibility, breastfeeding and pregnancy, the history of inherited or acquired connective tissue diseases, the use of any topical preparations on the face except sunscreen in Last three months, performing beautiful beauty treatments such as laser and photodynamic therapy in a past year, filler injections or fat in the last five years are excluded from the study process. First, the target area is marked on both sides of the patient's face and underneath Subcutaneous local sensory involvement with lidocaine 1% with epinephrine 1: 100,000. The sub system is conducted in this study by the DR BB Subsicion Device, which is a blind spindle and is specially designed to have a proximal section of the circular shape and gradually to the distal end and allow the path to move It has a tissue. The device is applied to the skin from the nosebleed nosebleed in the horizontal position to the lip of the lips and about two centimeters long. This treatment is repeated for 2 sessions with a 2-week interval. To be Patients will be examined before treatment and 1 month after the end of treatment. The results will be evaluated quantitatively and qualitatively. In a qualitative way, standard patient photography is performed with the VisioFace device and the patient will be asked about possible side effects. Photos are compared by two independent dermatologists. Ultimately, the rate of improvement is estimated as no response (recovery less than 10%) of low response (recovery between 25- 10%) moderate response (recovery between 25-75%) and excellent response (recovery rate greater than 75%) In addition, in order to determine the severity of wrinkles, dermatologists use the Wrinkle Severity Rating Scale (WSRS) system, which heavily scores between 0 and 5 scores.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705278146N19**
Registration date: **2017-08-14, 1396/05/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-14, 1396/05/23

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

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+98 21 2271 8021

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of efficacy and adverse effects of subsicion with blunt subcision blade in the correction of nasolabial fold depth

Public title

The evaluation of subsicion in the correction of nasolabial fold depth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diphtheria nasolabial hyperlipidemia, over 18 years old;Exclusion criteria: Dissatisfaction or willingness to continue the study for any reason; Use of racotene over the past 12 months; Presence of active skin infection in case; Lidocaine susceptibility; Lactation; And pregnancy; the history of inherited or acquired diseases of the connective tissue; the use of any topical preparations other than sunscreen during the last three months; performing beautiful facial procedures like lasers and photodynamic therapy in one year; injection of filler or Fat in the last 5 years;

Age

From **18 years** old to **70 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

Shahid Beheshti University of Medical Sciences

Street address

Daneshjoo Blvar.Velenjak

City

Tehran

Postal code

Approval date

2016-12-18, 1395/09/28

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.928

Health conditions studied

1

Description of health condition studied

Nasolabial fold

ICD-10 code

L90.8

ICD-10 code description

Other atrophic disorders of skin

Primary outcomes

1

Description

The severity of nasolabial wrinkles

Timepoint

Before treatment,One month after the end of treatment

Method of measurement

biometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Subsicion was performed in this study by a sub system. The device was inserted into the skin from the hole in the nasolabial nose in the hole created by the needle number 18, which is horizontal in the horizontal direction to the lip and at a distance of about two centimeters. This treatment can be repeated for 2 sessions at intervals of 2 weeks.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

laser application in medical sciences research center

Full name of responsible person

Dr.Behrouz Barikbin

Street address

Shohadaye Tajrish Hospital

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Afshin Zarghi
Street address
Daneshkoo Blvd.Velenjak
City
Tehran
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,Shahid Beheshti 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
Laser Application research center in medical science
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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