Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the efficacy and safety of the 980 nm Diode laser lipolysis and liposuction of submental area in shohada-Tajrish Hospital

Protocol summary

Summary

Objective: Sub mental fat accumulation and skin laxity is a sign of an aging neck and is a frequent concern of the cosmetic patients. Attempts to reduce this problem through diet and exercise alone are usually unsuccessful. Various cosmetic surgical procedure have been tried to reshape the lower aspect of the face like Traditional liposuction. Methods such as ultrasound-assisted liposuction, power assisted liposuction and laser-assisted liposuction aimed to reduce the side effects of the older methods. the most commonly advantages of these newly presented procedures include: diminished post-operative pain and recovery period, decreased extent of edema and bruising and blood loss that accompanied liposuction. Technological advances such as laser Diodes are now available in small and reliable packages at various wavelengths including 810,915,940,980 and studies showed that it can be a safe, effective and reproducible alternative to conventional liposuction. While treatment of skin laxity seems to be more important components than body contouring in submental area, a procedure that can induce collagen production and skin contraction is a better option. Method: the patients is categorized into two groups by the computer randomization program: group 1 undergo 980 nm diode laser lipolysis (LAL) (n=20) and aspiration and group 2 undergo liposuction alone (n=20). On the day of procedure, the area of target treatment is marked. Then patients are prep and draped in sterile fashion. Local tumescent anesthesia is composed of 1000 cc sodium chloride 0.9%, 100 cc lidocaine 1%, and 1cc epinephrine 1:1000. A total tumescent of 200-300cc is delivered to the submental area. Upon delivery of tumescent, an incision of 1-3mm is created at the target treatment area for the introduction of cannula. The 980nm diode laser (pharaon,OSYRIS, hellemmes,France) is used in continuous emission mode with power of 6-8 W. Laser energy is transmitted using a 600µm optical fiber encased in a 1 mm diameter microcannula through the incision into the subcutaneous fat moving at the rate at least of 1cm/s. the microcannula is moved in a backward and forward fan-like motion in the horizontal plane to achieve homogenous distribution of the laser energy. The treated area is held by operator's hand to attenuate the resistance of tissue and manually measure the skin temperature. When laser energy delivery is complete, the liquefied fat was aspirated with a 3mm cannula. Patients are evaluated at baseline, 1 week, 1 month, and 3 months after the procedure. At each visit they are photographed and clinically assessed by treating physician. The average fat thickness tissue is measured by ultrasonographic device at baseline and 1 month visit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305168146N13**
Registration date: **2013-06-02, 1392/03/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-06-02, 1392/03/12

Registrant information

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Name of organization / entity

Laser application in medical sciences research center

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Recruitment status

Recruitment complete

Funding source
lase application in medical science research center

Expected recruitment start date
2013-06-16, 1392/03/26

Expected recruitment end date
2014-06-16, 1393/03/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the efficacy and safety of the 980 nm Diode laser lipolysis and liposuction of submental area in shohada-Tajrish Hospital

Public title
Effect of 980 nm Diode laser lipolysis in submental area

Purpose
Treatment

Inclusion/Exclusion criteria
Female adults who express a desire for improving their submental contour were enrolled in this prospective randomized clinical trial. Patients with any previous treatment such as liposuction or lipolysis or in submental region were excluded from the study. Subjects with infection in the area, bleeding tendency,weight variation of more than 10% in the follow up evaluation, known allergy to local anesthetics, history of compromised wound healing, pregnancy and pregnancy were exluded.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University of Medical Sciences Ethics Committee

Street address
Daneshjoo Blvd., Velenjak st.

City
Tehran

Postal code

Approval date
2010-05-02, 1389/02/12

Ethics committee reference number
83

Health conditions studied

1

Description of health condition studied
Fat accumulation in submental area

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Fat reduction in patients

Timepoint
Before ,one week,one month, three months later

Method of measurement
Ultrasonography

2

Description
Objective assessment

Timepoint
Before, one week, one month, three months later

Method of measurement
Picturing the patients and assessment by blinded physician

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: patients with submental fat accumulation who undergot laser lipolysis On the day of procedure, the area of target treatment is marked. Then patients are prep and draped in sterile fashion. Local tumescent anesthesia is composed of 1000 cc sodium

chloride 0.9%, 100 cc lidocaine 1%, and 1cc epinephrine 1:1000. A total tumescent of 200-300cc is delivered to the submental area. Upon delivery of tumescent, an incision of 1-3mm is created at the target treatment area for the introduction of cannula. The 980nm diode laser (pharaon,OSYRIS, hellemmes,France) is used in continuous emission mode with power of 6-8 W. Laser energy is transmitted using a 600µm optical fiber encased in a 1 mm diameter microcannula through the incision into the subcutaneous fat moving at the rate at least of 1cm/s. the microcannula is moved in a backward and forward fan-like motion in the horizontal plane to achieve homogenous distribution of the laser energy. The treated area is held by operator's hand to attenuate the resistance of tissue and manually measure the skin temperature. When laser energy delivery is complete, the liquefied fat was aspirated with a 3mm cannula.

Category

Treatment - Surgery

2

Description

control group(traditional liposuction)the patient’s neck is marked with permanent marker to delineate the area to be treated, including the submental fat pad. The primary cannula entry point is located in the mental crease, approximately 0.5 cm directly posterior to the posterior border of the mandible at the chin. Liposuction is performed under sterile technique. After being marked, the patient’s face, neck, and chest is cleansed with chlorhexidine. Local tumescent anesthesia is composed of 1000 cc sodium chloride 0.9%, 100 cc lidocaine 1%, and 1cc epinephrine 1:1000. A total tumescent of 200-300cc is delivered to the submental area. The cannula is inserted into entry sites with the tip apertures facing downward, away from the dermis, to avoid inadvertent removal of superficial fat. Tunneling with the cannula is performed in linear, even strokes with the surgeon’s dominant hand, with the non dominant hand, or “smart hand,” controlling cannula tip position at all times. Multiple consecutive passes are made in each tunnel with aspiration before moving to the next location.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Laser application in medical sciences reserch center

Full name of responsible person

Street address

Shohada Tajrish medical center,Tajrish Sq

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Siences

Full name of responsible person

Marjan Kamyab

Street address

6 floor, No 2, shahid Beheshti University of medical sciences,Velenjak, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Siences

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

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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