

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation and comparison of the Effect of High Power Laser (2W) and Dry Needling on skin elasticity due to aging process in aged women

Protocol summary

Study aim

1. To evaluate the effect of high power laser (2W) and dry needling on epidermis and dermis thickness
2. To Assess the effect of High Power Laser (2W) and Dry Needling on Nasolabial fold area, depth, and elasticity
3. To determine the usage of High Power Laser (2W) and Dry Needling on patient's social function

Design

In this research, 25 women between 35-55 with Modified Fitzpatrick Wrinkle Scale between 2-2.5 mm, were selected and randomly divided to three groups of Laser, dry needling, and control. Group allocation was concealed by sealed numbered envelopes.

Settings and conduct

This study was conducted in Tarbiat Modares University. Subject randomizedly assigned to three groups. Ultrasonography was performed first session, and after the end of the three weeks of the intervention.

Participants/Inclusion and exclusion criteria

- 1- Women 35-55 years of age
- 2- BMI 25-30
- 3- Nasolabial Fold depth between 2 to 2.5 mm according to Modified Fitzpatrick Wrinkle Scale
- 4- Skin color type III and IV according to Fitzpatrick Classification Scale
- 5- No treatment for Nasolabial Fold at 6 month prior to the procedure
- 6- Not having any kinds of skin and inflammatory diseases, diabetes, HIV, and skin scars

Intervention groups

- 1- High Power Laser (2w) for Nasolabial Fold and associated muscles for seven sessions.
- 2- Dry needling for Nasolabial Fold and associated muscles for seven sessions.
- 3- Control group receives no treatment.

Main outcome variables

Laser dosage
Nasolabial Fold depth
Nasolabial Fold area
Strain Elasticity
Life Quality Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170818035759N2**

Registration date: **2018-02-08, 1396/11/19**

Registration timing: **retrospective**

Last update: **2018-02-08, 1396/11/19**

Update count: **0**

Registration date

2018-02-08, 1396/11/19

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 82882013

Email address

parinaz.omidi@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

2017-08-23, 1396/06/01

Actual recruitment end date

2018-01-06, 1396/10/16

Trial completion date

empty

Scientific title

Evaluation and comparison of the Effect of High Power Laser (2W) and Dry Needling on skin elasticity due to aging process in aged women

Public title

Effect of High Power Laser (2W) and Dry Needling on skin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women ages between 35-55 BMI between 25-30
Nasolabial Fold class between 2-2.5 according (Modified
Fitzpatrick Wrinkle Scale) No other treatment for
Nasolabial Fold (like Botox, Microneedling and cosmetic
surgery) for 6 month before this study

Exclusion criteria:

Systematic diseases like HIV, Diabetes, connective tissue
diseases like Lupus, Scleroderma, Sarcoidosis Surgical
and Non-Surgical Scars in treatment area Infectious
diseases in treatment area like (Cyst, skin Rashes,
Herpes) Pregnancyy Psychological disorders Metal alerjisi

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **25**

Actual sample size reached: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly assign subjects to two interventional and 1
control group By using envelops shuffling randomization ,
subjects pick up one envelope and enter one of three
groups by chance

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyzer has no information about the treatments
that subjects had

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University of
Medical Sciences

Street address

Jalal AleAhmad, Nasr

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2017-06-24, 1396/04/03

Ethics committee reference number

IR.TMU.REC.1396.559

Health conditions studied

1

Description of health condition studied

Decrease Skin Tissue Elasticity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Elasticity

Timepoint

25

Method of measurement

Ultrasound 40 MHz

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: High Power Laser (2w) for Nasolabial
Fold and associated muscles for seven sessions is used.
Applied energy to each nasolabial fold is 75 joule.

Category

Treatment - Devices

2

Description

Intervention group: Dry needling for Nasolabial Fold and
associated muscles for seven sessions is used.

Category

Treatment - Devices

3

Description

Control group: Control group recieves no treatment and
normal skin tissue is compared to intervention groups.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tarbiat Modares University Physiotherapy
Department

Full name of responsible person

Roya Ravanbod

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rravanbod@modares.ac.ir

Web page address

<http://www.modares.ac.ir/?siteid=56&pageid=6517&chcode=392362>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Vice Head of Research

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Grant name

Place of master thesis from research section of faculty of
medical science

Grant code / Reference number

000000

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

Yes

Title of funding source

Tarbiat Modares University

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**

Tarbiat Modares University

Full name of responsible person

Roya Ravanbod

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Title and more details about the data/document

Data of the study includes skin tissue elasticity, dermal and epidermal thickness and quality of life changes. The data of major outcome is shareable and personal information and before and after pictures are not shareable.

When the data will become available and for how long

access after thesis defence

To whom data/document is available

Physicaltherapy colleages and other researchers

Under which criteria data/document could be used

For research and treatment purposes

From where data/document is obtainable

There are two ways to access the data of study 1.

Parinaz Omid with Electronic Mail

parinaz.omidi@modares.ac.ir 2.Dr Roya Ravanbod with Electronic Mail rravanbod@modares.ac.ir

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

The applicant can access the data in one week by sendig E-mail to any of top Electronic Mails.

Comments