

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of Q switch laser and TCA peeling in the treatment of solar lentigo in the dorsal hands

Protocol summary

Study aim

Comparison of the effectiveness of Q-switch laser and peeling with TCA in the treatment of lentigo solar dorsal hands

Design

A randomized clinical trial with a random number table without blinding was followed in phase 2 with 45 patients, followed by a follow-up for 4 weeks.

Settings and conduct

In this study, 45 patients randomized with bilateral hand lentigo were selected. Then 35% TCA was randomly rubbed on all the lesions of one hand with the tip of a cotton swab. All other hand lesions were exposed to the Q SWITCH-ND: YAG 532 laser. Similar interventions were performed the next time with an interval of 4 weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria: symmetrical solar lentigo; based on clinical diagnosis; behind both hands. Exclusion criteria: associated physical illness, treatment in the last 6 months, drugs or alcohol consumption in the last 6 months, pregnancy or breastfeeding in women.

Intervention groups

Intervention group 1: Q-switch laser. Intervention group 2: peeling with TCA

Main outcome variables

Degree of pigmentation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201216049734N1**

Registration date: **2021-03-04, 1399/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-04, 1399/12/14**

Update count: **0**

Registration date

2021-03-04, 1399/12/14

Registrant information

Name

Azam Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

dr.azam.mosavi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-01, 1399/12/11

Expected recruitment end date

2021-06-24, 1400/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Q switch laser and TCA peeling in the treatment of solar lentigo in the dorsal hands

Public title

Treatment of solar lentigo using Q-switch laser

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with solar lentigo based on clinical diagnosis
Bilateral and symmetrical lesions

Exclusion criteria:
associated physical illness treatment in the last 6 months
Existence of substance or alcohol in the last six months
Pregnancy or breastfeeding in women

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
After preparing a list of appropriate patients, based on the inclusion criteria, 45 patients were selected and randomized based on a table of random numbers, in such a way that the laser was used for even-numbered numbers on the left hand and TCA solution was used on the opposite hand. The opposite was performed for odd numbers.

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
Ethics committee of Isfahan University of Medical Sciences

Street address
Sofe Street, Al-Zahra Hospital

City
Isfahan

Province
Isfahan

Postal code
8174675731

Approval date
2020-11-21, 1399/09/01

Ethics committee reference number
IR.MUI.MED.REC.1399.744

Health conditions studied

1

Description of health condition studied
solar lentigo

ICD-10 code
L81.4

ICD-10 code description
other melanin hyperpigmentation

Primary outcomes

1

Description
Degree of pigmentation

Timepoint
At the beginning of the study and the sixteenth week

Method of measurement
Clinical examination

2

Description
Pain

Timepoint
Fourth and eighth week

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Hyperpigmentation and hypo pigmentation

Timepoint
At the beginning of the study and the sixteenth wee

Method of measurement
clinical

Intervention groups

1

Description
Intervention group 1: On all lesions of one hand were rubbed with 35% TCA solution with the tip of a cotton swab.

Category
Treatment - Other

2

Description
Intervention group 2: All other hand lesions were exposed to the Q SWITCH-ND: YAG 532 laser (7-1 j / cm2energy and 3-4mmspot size).

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Azam Mosavi

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Sofeh Street, Al-Zahra Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Full name of responsible person

Azam Mosavi

Position

Dermatologist Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fariba Ireji

Position

Dermatologist

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Dermatologist Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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