

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

A comparison study of single, repeated and diascopic Q-switched laser therapy in tattoo removal in patients who referred to Razi Hospital

Protocol summary

2018-04-13, 1397/01/24

Study aim

Investigate the efficacy and safety of single, repeated and diascopic Q-switched laser therapy in tattoo removal

Design

A non-randomized, single-arm, non-blinded

Settings and conduct

The study is conducted at Razi hospital.

Participants/Inclusion and exclusion criteria

Inclusion criterion: candidates for tattoo removal using Q-switched laser radiation. Exclusion criteria: 1- colorful or faded tattoo 2- scars in the tattooed skin or area immediately surrounding it 3- unstable mental status 4- active infection 5- Pregnancy or lactation 6- History of an uncontrolled serious disorder.

Intervention groups

All the participants receive Q-switched laser radiation for three consecutive sessions six weeks apart. The tattooed lesion is divided into three parts. A 1/3 of the tattooed skin is treated with single Q-switched laser radiation in each session. The other 1/3 is received two laser radiations, 15 min apart. Finally, the last 1/3 part is treated with single laser radiation under diascopy.

Main outcome variables

Fading of the tattooed lesion with each intervention; the incidence of side effects with each treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180223038834N1**

Registration date: **2018-04-13, 1397/01/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-13, 1397/01/24**

Update count: **0**

Registration date

Registrant information

Name

Darya Khosravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5561 8989

Email address

dkhosravi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison study of single, repeated and diascopic Q-switched laser therapy in tattoo removal in patients who referred to Razi Hospital

Public title

A comparison study of diascopic Q-switched laser therapy in tattoo removal

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

candidates for tattoo removal using Q-switched laser radiation

Exclusion criteria:
 Colorful or faded tattoo Scars in the tattooed skin or area immediately surrounding it Unstable mental status
 Active infection Pregnancy or lactation History of an uncontrolled serious disorder

Age
 No age limit

Gender
 Both

Phase
 N/A

Groups that have been masked
 No information

Sample size
 Target sample size: **16**

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
 Ethics committee of Tehran University of Medical Sciences
Street address
 Faculty of Medicine, Tehran University of Medical Sciences, Poursina st.
City
 Tehran
Province
 Tehran
Postal code
 1417613151
Approval date
 2017-11-22, 1396/09/01
Ethics committee reference number
 IR.TUMS.MEDICINE.REC.1396.3959

Health conditions studied

1

Description of health condition studied
 Tattoo pigmentation
ICD-10 code
 L81.8

ICD-10 code description

Other specified disorders of pigmentation

Primary outcomes

1

Description
 The fading of the tattooed lesion
Timepoint
 18 weeks
Method of measurement
 Percentage of tattoo fading in close-up photographs taken before and after initiation of the interventions

Secondary outcomes

1

Description
 side-effects
Timepoint
 18 weeks
Method of measurement
 History and physical examination

Intervention groups

1

Description
 Intervention group: The tattooed lesion is divided into three parts. A 1/3 of the tattooed skin is treated with single Q-switched laser radiation in each session. The other 1/3 is received two laser radiations, 15 min apart. Finally, the last 1/3 part is treated with single laser radiation under diascopy.
Category
 Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
 Skin Razi Hospital
Full name of responsible person
 Darya Khosravi
Street address
 Razi hospital, Razi Ave, Vahdate eslami Ave, Hafiz Street
City
 Tehran
Province
 Tehran
Postal code
 1417613151
Phone
 +98 21 5561 8989
Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhound Zadeh

Street address

Research Vice-Chancellor, Room 205, First Floor,
Education Building, Faculty of Medicine, Tehran
University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 6640 0917

Email

s.akhond@neda.net

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Darya Khosravi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Razi hospital, Razi Ave, Vahdate eslami Ave, Hafiz
Street

City

Teharn

Province

Tehran

Postal code

1417613151

Phone

+98 21 5561 8989

Email

dkhosravi@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Darya Khosravi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Razi hospital, Razi Ave, Vahdate eslami Ave, Hafiz
Street

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 5561 8989

Email

dkhosravi@razi.tums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Darya Khosravi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Razi hospital, Razi Ave, Vahdate eslami Ave, Hafiz
Street

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 5561 8989

Email

dkhosravi@razi.tums.ac.ir

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

IPD collected for the primary outcome measure only

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

Scientific research

From where data/document is obtainable

Dr. Darya Khosravi

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

The application is sent by official university email which should contain the recipient's information and the purpose of his/her request. After having verified the accuracy of the information, files would be sent.

Comments