Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison between efficacy and safety of 585-nanometer pulsed dye laser alone and with cryotherapy in treating superficial basal cell carcinoma

Protocol summary

Summary

The aim of this study is to evaluate the efficacy and safety of 585-nanometer Pulsed dye laser alone and with cryotherapy in treating superficial basal cell carcinoma. Study design will be random clinical trial, double-blinded, without control with placebo and single-center. Study population will be chosen out of those patients affected by superficial basal cell carcinoma who refer to the Dermatology Clinic of Imam Khomeini Hospital in Ahvaz and meet the inclusion criteria including pathologically ducumented basal cell carcinoma and maximum tumor diameter of 30 millimeters. The main exclusion criteria will include skins with Fitzpatrick type of more than 3, coagulation disorders or recent receiving of anticoagulant, and consumption of drugs sensitive to light. Sample size will be 32 tumor of superficial basal cell carcinoma. Patients will randomly be divided into two groups and the first group will be treated by 585-nanometer pulsed dye laser alone, and the second group will also be cryotherapied in addition to laser. There will be two treatment sessions with intervals of 3 weeks. Six months after the last treatment session, histologic and clinical assessment will be performed. Primary outcome of this study is tumor remission 6 months after the last treatment session. The second outcome is studying the safety (side effects) of applied therapeutic methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030732933N1**
Registration date: **2017-05-21, 1396/02/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-21, 1396/02/31

Registrant information

Name

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Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between efficacy and safety of 585-nanometer pulsed dye laser alone and with cryotherapy in treating superficial basal cell carcinoma

Public title

The effect of laser alone and with cryotherapy in treating superficial basal cell carcinoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Pathologically documented basal cell carcinoma; maximum tumor diameter of 30 millimeters Exclusion criteria: Skins with Fitzpatrick type of higher than 3; coagulation disorders or recent receiving of anti-coagulant agents; consumption of light-sensitive drugs

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz, Iran

City

Ahvaz

Postal code

Approval date

2016-12-03, 1395/09/13

Ethics committee reference number

IR.AJUMS.REC.1395.719

Health conditions studied

1

Description of health condition studied

superficial basal cell carcinoma

ICD-10 code

C43-C44

ICD-10 code description

Melanoma and other malignant neoplasms of skin

Primary outcomes

1

Description

tumor remission

Timepoint

6 months after the last treatment session

Method of measurement

Clinical observations and pathology

Secondary outcomes

1

Description

Scar

Timepoint

After each treatment session and 6 months after the last treatment session

Method of measurement

Clinical observation

Intervention groups

1

Description

585-nanometer PDL laser with power of 9 joules, in 450 microseconds, for 2 treatment sessions with 3-week intervals

Category

Treatment - Devices

2

Description

585-nanometer PDL laser with power of 9 joules, in 450 microseconds, followed by cryotherapy with one unit of liquid nitrogen (CRY-ACW) using spray method during two freeze cycles each of which being 4±2 minutes, for 2 sessions with intervals of 3 weeks

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Imam Khomeini Hospital

Full name of responsible person

Seyed Mohammad Radmanesh

Street address

Dermatology Clinic of Imam Khomeini Hospital, Azadegan St, Ahvaz, Khuzestan, Iran

City

Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Masud Eslamizadeh
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Imam Khomeini Hospital, Azadegan Street, Ahvaz
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Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jundishapur 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
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Person responsible for scientific inquiries

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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