

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of Photodynamic therapy with topical Indocyanine green in the treatment of Keloidal lesions

Protocol summary

Study aim

Efficacy of Photodynamic therapy with topical indocyanine green in the treatment of Keloidal lesions

Design

clinical trial, pilot study

Settings and conduct

before the therapeutic sessions, small amount of ICG ointment applied in lateral side of arm and the patient being informed not to touch or rinse the place. after 48 hours we look the place for any kind of skin reactions and if there was no skin reactions the patient is allowed to enter to trial. first a basic photograph of the lesion being taken and the dimensions are determined. lesions being covered with ICG ointment with 1mm thickness on top and 5mm around and its covered with biofilm for 1 hour. then the lesions being wiped off and it goes under photodynamic therapy with source LumaCare with 730 nm probe every 2 weeks and total of 6 sessions. patients being assessed in 6 and 12 weeks after the treatment sessions for any recurrences. the place we do the trial is in dermatology outpatient clinic of imam Reza hospital in Mashhad

Participants/Inclusion and exclusion criteria

The patients with minimum age of 18 years old are being selected based on dermatologist diagnosis as having idiopathic keloids. They have no history of any medical treatments for their lesions in 3 last months. only lesions that are located on trunk, extremities, back and buttock are being selected.

Intervention groups

patients who undergo using indocyanine green ointment and photodynamic therapy

Main outcome variables

determining efficacy of Photodynamic therapy with topical indocyanine green in the treatment of Keloidal lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201221049780N1**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

Registration date

2021-03-17, 1399/12/27

Registrant information

Name

Sara Fakhraei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Photodynamic therapy with topical Indocyanine green in the treatment of Keloidal lesions		City Mashhad	
Public title Efficacy of Photodynamic therapy with topical Indocyanine green in the treatment of Keloidal lesions		Province Razavi Khorasan	
Purpose Treatment		Postal code 9177899191	
Inclusion/Exclusion criteria Inclusion criteria: the patients are selected based on dermatologist diagnosis as having idiopathic keloids minimum age for being selected is 18 years old patients have no history of any medical treatments for their lesions at least in 3 months lesions are on trunk, extremities, back and buttock Exclusion criteria: any skin disease or abnormality around the lesion for example dermatitis, bacterial or fungal infections pregnancy lactation lesions on face and genitalia history of any medical treatments for their lesions in 3 last months		Approval date 2020-12-21, 1399/10/01	
Age From 18 years old		Ethics committee reference number IR.MUMS.MEDICAL.REC.1399.542	
Gender Both		Health conditions studied <u>1</u> Description of health condition studied keloid ICD-10 code L91.0 ICD-10 code description Hypertrophic scar	
Phase 2		Primary outcomes <u>1</u> Description improvement of keloidal lesions based on POSAS score	
Groups that have been masked No information		Timepoint before the trial, every month after starting trial, in 6th and 12th weeks after finishing the trial	
Sample size Target sample size: 15 More than 1 sample in each individual Number of samples in each individual: 2 2 keloidal lesions of any patients are being selected		Method of measurement Patient and Observer Scar Assessment Scale	
Randomization (investigator's opinion) N/A		Secondary outcomes empty	
Randomization description		Intervention groups <u>1</u> Description Intervention group: patients under treatment with indocyanine green 0.2% ointment and photodynamic therapy after 1 hour, every 2 weeks for total of 6 sessions	
Blinding (investigator's opinion) Not blinded		Category Treatment - Drugs	
Blinding description		Recruitment centers <u>1</u> Recruitment center Name of recruitment center Dermatology Clinic of Imam Reza Hospital of Mashhad City Full name of responsible person Ahmad Reza Taheri Street address	
Placebo Not used			
Assignment Single			
Other design features			
Secondary Ids empty			
Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Mashhad University of Medical Sciences Street address Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street			

Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue

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Sara Fakhraei

Position

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Latest degree

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Person responsible for scientific inquiries

Contact

Name of organization / entity

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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