Clinical Trial Protocol
Iranian Registry of Clinical Trials
29 Mar 2022

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 od 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
Country
Iran (Islamic Republic of)
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+98 51 3876 0858
Email address
sarai.fakhraei@gmail.com

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

Purpose
Treatment

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

Age
From 18 years old

Gender
Both

Phase
2

Groups that have been masked
No information

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

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 Mashhad University of Medical Sciences

Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City
Mashhad

Province
Razavi Khorasan

Postal code
9177899191

Approval date
2020-12-21, 1399/10/01

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.542

Health conditions studied

1

Description of health condition studied
keloid

ICD-10 code
L91.0

ICD-10 code description
Hypertrophic scar

Primary outcomes

1

Description
improvement of keloidal lesions based on POSAS score

Timepoint
before the trial, every month after starting trial, in 6th and 12th weeks after finishing the trial

Method of measurement
Patient and Observer Scar Assessment Scale

Secondary outcomes
empty

Intervention groups

1

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

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology Clinic of Imam Reza Hospital of Mashhad

City
Mashhad

Full name of responsible person
Ahmad Reza Taheri

Street address
Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue
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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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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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9137913316
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ramresearch@mums.ac.ir
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 scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Ahmadreza Taheri Bojd
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
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Person responsible for updating data

Contact
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Position
dermatology resident
Latest degree
Medical doctor
Other areas of specialty/work

Person responsible for general inquiries

Contact
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Position
dermatology resident
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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