Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

To assess the effect of intense pulse light therapy in Iranian patients with meibomian gland dysfunction.

Protocol summary

Study aim
To assess the changes of ocular surface and tear film in patients with meibomian glands dysfunction (MGD), who are given intense pulse light therapy, and to compare it with controls.

Design
This Clinical trial consists of parallel groups (Fifty patients with MGD in control and intervention groups), which will be simply randomized for the intervention and will be double blinded.

Settings and conduct
Noorafarin eye clinic, Mashhad

Participants/Inclusion and exclusion criteria
One hundred patients with MGD will be recruited if they are eligible for the study: Inclusion criteria: Having ethical consent for participation in the study, having history of MGD treatment for at least two months. Exclusion criteria: Having any systemic or ocular disease or history of ophthalmic surgeries. contact lens users, Taking medications with photo sensitivity side effect, like steroids and retinoids Having tattoos in palpebral and peri orbital region. Lactation and pregnancy

Intervention groups
Fifty patients who are given intense pulse light therapy for meibomian gland dysfunctions. Fifty MGD patients in control group are not given IPL therapy, but they will underwent the conventional treatment for MGD.

Main outcome variables
Tear meniscus height, tear break up time, OSDI score, meibography upper and lower lid, meibomian gland expressibility, SM tube meniscometry, tear osmolarity, bulbar and conjunctival redness, conjunctival chalasis.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190507043503N1**
Registration date: **2019-07-13, 1398/04/22**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-13, 1398/04/22**
Update count: **0**

Registration date
2019-07-13, 1398/04/22

Registrant information

Name
Samira Hassanzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date
2020-01-21, 1398/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
To assess the effect of intense pulse light therapy in Iranian patients with meibomian gland dysfunction.

Public title
To assess tear film changes after intense pulse light therapy in Iranian patients with meibomian gland

dysfunction.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a diagnosis of meibomian gland dysfunction according to international diagnostic criteria Patients who have ethical consent for participating in the study Patients who have the history of at least 2 months taking current medications for meibomian gland dysfunction.

Exclusion criteria:

Having any ocular or systemic disease Having any history of ophthalmic surgeries Taking medications with photo sensitivity side effects Contact lens wearers Having nevus or tattoos in palpebral and peri orbital region

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using pocket. For each patient, we will put the label of intervention and control groups in a pocket and the practitioner will randomly takes out a label from the pocket. The patient will be allocated to the selected group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in both intervention and control groups will be given the current medications for meibomian glands dysfunction and they will not be aware of their allocation. The investigator who will follow the patients and perform the tests, will be also unaware about the groups allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

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#155, Mahdi 2 ave., Mahdi st, Ferdowsi Blvd.

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Razavi Khorasan

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Approval date

2019-06-18, 1398/03/28

Ethics committee reference number

IR.MUMS.REC.1398.081

Health conditions studied

1

Description of health condition studied

Meibomian gland dysfunction

ICD-10 code

H04.1

ICD-10 code description

Evaporative dry eye- dry eye syndrome

Primary outcomes

1

Description

OSDI score: this ocular surface index questionnaire consists of 12 question and assesses the severity of dry eye.

Timepoint

Baseline, day 14, day 45, day 75

Method of measurement

sum of score of questionnaire which has been filled by the patients

2

Description

TBUT : tear break up time

Timepoint

Baseline, day 14, day 45, day 75

Method of measurement

keratograph, slit lamp

3

Description

osmolarity: tear film density

Timepoint

baseline, day 75

Method of measurement

tear lab device

Secondary outcomes

1

Description
meibomian gland drop out which is graded from 0 to 3.
Timepoint
baseline, day 14, day 45, day 75
Method of measurement
keratograph device

2

Description
PSQI: Pittsburgh sleep quality index
Timepoint
BASELINE, DAY 75
Method of measurement
Sum of score of questionnaire which has been filed by the patients

Intervention groups

1

Description
Intervention group: 50 patients with meibomian gland dysfunction will undergo 3 sessions of intense pulse light therapy. Meanwhile routine dry eye therapy consisting using artificial tears, massage and warm compress will be continued.
Category
Treatment - Devices

2

Description
Control group: 50 patients with meibomian gland dysfunction who will undergo routine dry eye therapy consisting using artificial tears, massage and warm compress and will follow up similar to intervention group.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Noorafarin eye clinic
Full name of responsible person
Samira Hassanzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Research Deputy of Mashhad University of Medical Sciences.
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Ghoreyshi department, Daneshgah 18 st, Daneshgah Ave.
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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
Samira Hassanzadeh
Position
Ph.D. student
Latest degree
Master
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Optometry
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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
Data will be available after data analysis.

When the data will become available and for how long
Starting 6 months after publication

To whom data/document is available
For academic staff

Under which criteria data/document could be used
Data will be available on researchers' request.

From where data/document is obtainable
Sending request via research gate website

What processes are involved for a request to access data/document
Access will be possible on request .

Comments