

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

Country

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

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

City
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Razavi Khorasan

Postal code
9197984767

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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No. 231, Mahdi intersection, Ferdowsi blvd.

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Web page address

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.

Street address

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

Other areas of specialty/work

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