

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 undergo 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)

##### Phone

+98 51 3768 3848

##### Email address

hasanzadehs951@mums.ac.ir

#### 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**

Mashhad

#### **Province**

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

#### Street address

No. 231, Mahdi intersection, Ferdowsi blvd.

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#### Postal code

9197985768

#### Phone

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#### Email

info@noorafarineyeclinic.com

## 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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#### Postal code

9196984476

#### Phone

+98 51 3841 2081

#### Email

vcresearch@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 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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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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