

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Effectiveness of Photorefractive Keratectomy on Hypermetropia by Wavelight Excimer Laser system

Protocol summary

Study aim

The objective of this clinical trial is evaluation of the effect Photorefractive Keratectomy on Hypermetropia using Wavelight Excimer Laser system.

Design

Randomised, open label clinical trial, phase 2 with a single group design of 20 patients with Hypermetropia.

Settings and conduct

All of these patients will operated PRK (photorefractive keratectomy) by Wavelight Excimer Laser system in Alavi hospital of Ardabil city. 30 minutes postoperative, 1 week, 1 month, 3 months, 6 months and one year postoperative results were compared with preoperative data.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hypermetropia patients up to 6.00 diopters and older than 18 years. Exclusion criteria: History of corneal surgery; herpetic eye disease; corneal dystrophy and scar; keratoconus; severe dry eye and collagen vascular disease.

Intervention groups

All of these patients will operated PRK (photorefractive keratectomy) by Wavelight Excimer Laser system.

Main outcome variables

Patients will be examined for The Hypermetropia clinical manifestations after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160318027097N9**

Registration date: **2018-04-11, 1397/01/22**

Registration timing: **prospective**

Last update: **2018-04-11, 1397/01/22**

Update count: **0**

Registration date

2018-04-11, 1397/01/22

Registrant information

Name

Dr Faramarz Darghahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 2000

Email address

mj.naghizadeh@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Effectiveness of
Photorefractive Keratectomy on Hypermetropia by
Wavelight Excimer Laser system

Public title

Effect of Photorefractive Keratectomy on Hypermetropia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age older than 18 years; Hypermetropia up to 6.00 diopters

Exclusion criteria:
History of corneal surgery; herpetic eye disease; corneal dystrophy and scar; keratoconus; severe dry eye and collagen vascular disease.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

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 Ardebil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Daneshgah Avenue, Ardabil , Iran

City

Ardabil

Province

Ardabil

Postal code

5163639888

Approval date

2017-11-13, 1396/08/22

Ethics committee reference number

IR.ARUMS.REC.1396.147

Health conditions studied

1

Description of health condition studied

Hyperopia

ICD-10 code

H52.0

ICD-10 code description

Hypermetropia

Primary outcomes

1

Description

The Hypermetropia clinical manifestations

Timepoint

30 minutes postoperative, 1 week, 1 month, 3 months, 6 months and one year postoperative

Method of measurement

Clinical examinations

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Photorefractive keratectomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Vice Chancellor for research of Ardebil University of Medical Sciences

Full name of responsible person

Dr Habib Ojaghi

Street address

Ardabil University of Medical Sciences, Daneshgah Avenue, Ardabil, Iran

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naghizadeh73@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Habib Ojaghi

Street address

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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

Ardebil 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

Ardebil University of Medical Sciences

Full name of responsible person

Dr Rahim Masomi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Ardebil University of Medical Sciences

Full name of responsible person

Behrad Shahin

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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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

Total potential data after unidentifiable individuals

When the data will become available and for how long

Start the access period from 2021

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

Data can be used for scientific and research studies.

From where data/document is obtainable

Behrad Shahin; Medical student;

Naghizadeh73@yahoo.com

What processes are involved for a request to access data/document

After receiving the request email, data files will be sent in less than a week.

Comments