

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluating the effect of hyperopic orthokeratology contact lenses on near vision, refraction, topography and corneal thickness for correcting the presbyopia using monovision technique in non dominant eye

Protocol summary

Study aim

To evaluate the effect of hyperopic orthokeratology lenses based on Monovision technique in correction of presbyopia

Design

Non randomized sampling was performed. The non-dominant eye was assigned to the intervention group and the dominant eye to the control group. The technique which was used for intervention was monovision.

Settings and conduct

After completing informed consent form, primary examination was conducted in optometry clinic and Mashhad Razavi hospital. Then hyperopic orthokeratology lenses were ordered and non-dominant eyes were fitted with these lenses. Following from this, fluorescein pattern were evaluated and after that, participants were asked to wear contact lenses for 7 nights (at least 6 hours per night). Participants were followed for one week and ocular examination was done at first and seventh day after wearing lenses

Participants/Inclusion and exclusion criteria

Inclusion criteria: emmetropic persons with blurred near vision; age range of 43-50 years old; completing informed consent form; uncorrected distance visual acuity at least 6/9. Exclusion criteria: Against the rule astigmatism; any kind of ocular and systemic disease; ocular surgery history;; previous history of wearing RGP or hard contact lenses; with the rule astigmatism more than 1.5 diopter

Intervention groups

Intervention group: non dominant eye. Control group: dominant eye. Non dominant eye is fitted with orthokeratology contact lenses. This study included a total of 11 participants that right eye and left eye were non-dominant in 2 and 9 patients, respectively. Dominant eye was considered as a control group (without intervention).

Main outcome variables

Changes in near visual acuity; central axial curvature; peripheral axial curvature and central corneal thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200228046640N1**

Registration date: **2020-04-27, 1399/02/08**

Registration timing: **retrospective**

Last update: **2020-04-27, 1399/02/08**

Update count: **0**

Registration date

2020-04-27, 1399/02/08

Registrant information

Name

nasrin mohammadpanah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3620 1371

Email address

opto_nmp@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-13, 1398/01/24

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2019-04-13, 1398/01/24

Actual recruitment end date

2019-09-19, 1398/06/28

Trial completion date

2019-12-21, 1398/09/30

Scientific title

Evaluating the effect of hyperopic orthokeratology contact lenses on near vision, refraction, topography and corneal thickness for correcting the presbyopia using monovision technique in non dominant eye

Public title

The effect of orthokeratology night time contact lenses for correcting presbyopia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Emetropic persons age range of 43-50 years Unaided distance visual acuity in dominant eye at least 6/9 Blurred near vision

Exclusion criteria:

The amount of with the rule astigmatism more than 1.5 diopter Presence of against the rule astigmatism eye disease systemic disease ocular surgery history History of wearing RGP or hard contact lenses

Age

From **43 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **11**

Actual sample size reached: **11**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National ethics committee in biomedical research, Mashhad University of Medical Sciences

Street address

Optometry group, paramedical college, university campus, Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948964

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.MUMS.REC.1397.310

Health conditions studied**1****Description of health condition studied**

Presbyopia

ICD-10 code

H52.4

ICD-10 code description

Presbyopia

Primary outcomes**1****Description**

Near visual acuity

Timepoint

Before intervention, one day and 7 days after intervention

Method of measurement

Visual acuity chart

2**Description**

Central axial curvature

Timepoint

Before intervention, one day and 7 days after intervention

Method of measurement

Topography

3**Description**

Peripheral axial curvature

Timepoint

Before intervention, one day and 7 days after intervention

Method of measurement

Topography

Secondary outcomes**1****Description**

Refraction

Timepoint

Before intervention, one day and 7 days after intervention

Method of measurement

Auto reFractometer

Intervention groups

1

Description

Intervention group :non-dominant eye .This is a "contralateral eye study" that non-dominant eye is fitted with hyperopic orthokeratology Boston xo contact lenses. This study included a total of 11 participants that right eye and left eye were non-dominant in 2 and 9 patients, respectively.

Category

Treatment - Devices

2

Description

Control group: Dominant eye was conducted as a control group with out any intervention.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of optometry

Full name of responsible person

Nasrin Mohammadpanah

Street address

Optometry department; Paramedical School; university campus; Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948964

Phone

+98 51 3884 6710

Fax

+98 51 3884 6728

Email

sps.Dean@MUMS.AC.IR

Web page address

<https://optometrydept.mums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hadi Ostadi Moghadam

Street address

Paramedical School; university campus; Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948964

Phone

+98 51 3884 6710

Fax

+98 51 3884 6728

Email

sps.Dean@mums.ac.ir

Web page address

<https://optometrydept.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

Hadi ostadi moghadam

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Optometry

Street address

Paramedical collage, Pardis university.Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948964

Phone

+98 51 3884 6710

Email

ostadih@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nasrin mohammadpanah

Position

optometrist

Latest degree

Master

Other areas of specialty/work

Optometry

Street address

Optometry department; Paramedical School;
university campus; Azadi square

City

Mashhad

Province

Razavi Khorasan

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Phone

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Email

opto_nmp@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nasrin Mohammadpanah

Position

optometrist

Latest degree

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Primary and secondary variables data

When the data will become available and for how long

Beginning of access course from 1400

To whom data/document is available

Just for researchers

Under which criteria data/document could be used

For study with more samples and longer follow up course

From where data/document is obtainable

Tel:09157063117 Email:opto_nmp@yahoo.com

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

One month after request

Comments