

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of efficacy of two types of silicone hydrogel contact lenses Lotrafilcon B and Balafilcon A after photorefractive keratectomy

Protocol summary

Summary

The purpose of this study is to compare the efficacy of two silicone hydrogel bandage contact lenses Lotrafilcon B and Balafilcon A in reducing pain and ocular discomfort after photorefractive keratectomy. This study is a double blinded clinical trial without control group. Patients willing to go under photorefractive surgery will enter the trial after signing the informed consent. Inclusion criteria are basically the criteria for refractive surgery. Exclusion criteria are any systemic or corneal disease. Based on previous studies and considering $\alpha=0.05$, sample size was estimated to be 120 eyes. After the surgery, Lotrafilcon B contact lens was fitted in one eye of each patient and Balafilcon A contact lens in the fellow eye. The patients were asked to answer a questionnaire on the first and third day after surgery about the onset of pain, the time of maximum pain, severity of ocular symptoms (pain, epiphora, foreign body sensation, blurred vision, photophobia) and overall satisfaction from 0 to 10. The examiner will remain blinded to patients' lens type through the study. Blinding will also be done in analyzing. After gathering the data, the efficacy of aforementioned lenses will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122413567N8**

Registration date: **2014-10-10, 1393/07/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-10, 1393/07/18

Registrant information

Name

Mehrdad Mohammadpour

Name of organization / entity

Tehran university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5542 6286

Email address

mohammadpour_m@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Eye Research Center, Farabi hospital

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of two types of silicone hydrogel contact lenses Lotrafilcon B and Balafilcon A after photorefractive keratectomy

Public title

Comparison of efficacy of two types of contact lenses on reducing pain and discomfort of patients after photorefractive keratectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age 19 to 40 years old; refraction stability of at least 1 year; myopia of 8 diopter or less/astigmatism of 6 diopter or less; minimum corneal

thickness of 480 micrometer in ultrasound pachymetry; minimum residual stromal thickness of 420 micrometer; corrected distant visual acuity equal or more than 20/20
Exclusion criteria: Ocular diseases such as cataract and glaucoma; corrected distant visual acuity of less than 20/20; diseases that could delay recovery such as diabetes mellitus, collagen vascular diseases, autoimmune diseases, herpetic eye infection and immune deficiency; history of colloid formation following previous surgeries

Age

From **19 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

N/A

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee at Tehran university of medical science

Street address

University's central building, Qods Ave., Keshavarz Ave., Enghelab Ave.

City

Tehran

Postal code**Approval date**

2014-04-18, 1393/01/29

Ethics committee reference number

114/130/93/5

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

myopia, hyperopia

ICD-10 code

H54.3

ICD-10 code description

mild or no visual impairment, binocular

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

Pain

Timepoint

1st postoperative day, 3rd postoperative day

Method of measurement

Questionnaire

2**Description**

Epiphora

Timepoint

1st postoperative day, 3rd postoperative day

Method of measurement

Questionnaire

3**Description**

Foreign body sensation

Timepoint

1st postoperative day, 3rd postoperative day

Method of measurement

Questionnaire

4**Description**

Blurred vision

Timepoint

1st postoperative day, 3rd postoperative day

Method of measurement

Questionnaire

5**Description**

Photophobia

Timepoint

1st postoperative day, 3rd postoperative day

Method of measurement

Questionnaire

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

Satisfaction

Timepoint

1st postoperative day, 3rd postoperative day

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group 1: consists of one eye of each patient which is fitted with Lotrafilcon B silicone hydrogel contact lens (Air Optix®AQUA, Ciba Vision, Duluth, GA, USA) by a surgeon who is aware of the type of contact lenses after photorefractive keratectomy. The bandage contact lens will be removed after complete reepithelialization. Postoperative protocol includes Betamethasone eye drop 4 times daily which will be tapered over 3 weeks and changed to Fluorometholone 0.1% eye drop and Chloramphenicol eye drop 4 times daily for 5 days.

Category

Treatment - Other

2

Description

Intervention group 2: consists of one eye of each patient which is fitted with Balafilcon A silicone hydrogel contact lens (PureVision™ Bausch & Lomb, Rochester, NY, USA) by a surgeon who is aware of the type of contact lenses after photorefractive keratectomy. The bandage contact lens will be removed after complete reepithelialization. Postoperative protocol includes Betamethasone eye drop 4 times daily which will be tapered over 3 weeks and changed to Fluorometholone 0.1% eye drop and Chloramphenicol eye drop 4 times daily for 5 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi hospital

Full name of responsible person

Dr.Mehrdad Mohammadpour

Street address

excimer clinic, Farabi hospital, Qazvin Sq.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Dr. Masud Yunesian

Street address

Seventh floor, University's Central Building, Qods Ave., Keshavarz Ave., Enghelab Ave.

City

Tehran

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor for research of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehrdad Mohammadpour

Position

Associate Professor

Other areas of specialty/work

Street address

Eye Research Center, Farabi hospital, Qazvin Sq.

City

Tehran

Postal code

Phone

+98 21 5542 1006

Fax

Email

mohammadpour_m@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Eye Research Center, Farabi hospital

Full name of responsible person

Mehrdad Mohammadpour

Position

Anterior Segment & Cornea Fellowship

Other areas of specialty/work

Street address

Farabi eye hospital, Qazvin Sq.

City

Tehran

Postal code

Phone

+98 21 5542 1006

Fax

Email

mahammadpour@yahoo.com

Web page address

00

Fax

Email

afsane_amz@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Afsaneh Amouzegar

Position

MD student

Other areas of specialty/work

Street address

Tehran University of Medical Sciences, Porsina Ave.,
Keshavarz Blvd., Enghelab Ave.

City

Tehran

Postal code

Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty