Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Biomechanical characteristics changes with Ocular Response Analyzer in keratoconic eyes after Intrastromal corneal Ring segment (keraring) implantation.

Protocol summary

Summary

use of intra stromal corneal ring in patient with clear cornea that unable to use glass or hard contact lens or because irrigularity and high abrasion,glass can not improve visual acuity.so intra stromal corneal ring is one of methods can improve irrigularity of cornea,decreased asthigmatism,improvment of visual acuity,delay of corneal transplantaion.this method newly Take into consideration and few previous studies was surveyed.goal of this study is survey of biomechanical karactristic cornea after 6 months from placement of intra stromal corneal ring,in preoperation survey evaluate refractive error,the best visual acuity.topography performed with pentacam.size ,thickness and number of rings adjusted based on refractory error,thickness of cornea and keraring nomograghy with Manufacturer.two biomechanical factors such as Corneal Hysteresis (CH) و Corneal Resistance Factor (CRF) assess with Ocular Response Analyzer preoperation,1month,6month post operation,necessary information recordin related form pre-post operation,then information analize with spss 17

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071510143N2**
Registration date: **2013-08-31, 1392/06/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-31, 1392/06/09

Registrant information

Name
Tahmineh Aryan
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 3655 8124
Email address
afshin_lotfi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source
Tabriz University of Medical Sciences

Expected recruitment start date

2013-08-19, 1392/05/28

Expected recruitment end date

2013-10-20, 1392/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Biomechanical characteristics changes with Ocular Response Analyzer in keratoconic eyes after Intrastromal corneal Ring segment (keraring) implantation.

Public title

Biomechanical characteristics changes with Ocular Response Analyzer in keratoconic eyes after Intrastromal corneal Ring segment (keraring) implantation.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-patient satisfaction 2-Progressive

deterioration of vision so that the patient dose not necessary visual function with contact lenses or glasses for the daily work 3-patient with clear central cornea 4-cornea thickness equal or more than 450 micrometer in 5 sites incision 5-absent of local or diffuse autoimmune disease exclusion criteria: 1-post refractive surgery ectasia 2-previous corneal transplantation 3- corneal opacity 4- cornea thickness lesser than 450 micrometer in 5 sites incision 5- local or diffuse autoimmune disease

Age
From **21 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **21**

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 Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences,avenue golgasht,tabriz

City
tabriz

Postal code

Approval date
2013-08-19, 1392/05/28

Ethics committee reference number
9284

Health conditions studied

1

Description of health condition studied
keratocunos

ICD-10 code
H18.6

ICD-10 code description
keratocunos

Primary outcomes

1

Description
Corneal Hysteresis (CH) و Corneal Resistance Factor (CRF)

Timepoint
preoperation,1&6 month post operation

Method of measurement
Ocular Response Analyzer (ORA)

Secondary outcomes

1

Description
visual acuity

Timepoint
preoperation,1&6 month post operation

Method of measurement
snellen chart

Intervention groups

1

Description
clinical trial study, The design of this study is cross over,two biomechanical factors such as Corneal Hysteresis (CH) و Corneal Resistance Factor (CRF) assess after placement of keraring intra stromal cornea ring in keratoconic patient at 1th & 6th month

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Nikukari Eye Hospital

Full name of responsible person
dr afshin lotfi

Street address
Nikukai Hospital, Abbasi St.,tabriz

City
tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medica lSciences(chancellor for

research

Full name of responsible person

Vice chancellor for research /dr seyed kazem shokori

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht St.,tabriz

City

tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medica lSciences(chancellor for research

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

Tabriz University of Medical Sciences

Full name of responsible person

dr mohammad vashagh

Position

MB, resident of Ophthalmology

Other areas of specialty/work

Street address

Nikukari Eye Hospital, Abbasi St.,tabriz

City

tabriz

Postal code

Phone

+98 41 1655 1332

Fax

Email

mveshagh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

dr afshin lotfi

Position

Ophthalmologist

Other areas of specialty/work

Street address

Nikukari hospital, Abbasi St.,tabriz

City

tabriz

Postal code

Phone

+98 41 1655 1332

Fax

Email

afshin_lotfi@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

dr mohammad veshagh

Position

MB, resident of Ophthalmology

Other areas of specialty/work

Street address

Nikukari Eye Hospital, Abbasi St.,tabriz

City

tabriz

Postal code

Phone

+98 41 1655 1332

Fax

Email

mveshagh@gmail.com

Web page address

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