

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of effect of onset of losartan systemic administration on intraocular pressure in hypertensive patients

Protocol summary

2021-12-21, 1400/09/30

Study aim

Determining the onset of losartan systemic administration effect on intraocular pressure in hypertensive patients refer to Feiz hospital in 1400

Design

Randomized, single group, 42 patients, not blinded, phase 2

Settings and conduct

Cardiologist selects hypertensive patients refer to cardiology clinic of Feiz hospital, Esfahan, that have indication of losartan therapy, then refer to glaucoma clinic of Feiz hospital for intraocular pressure measurement by ophthalmologist on beginning of study then follow up after 1 and 3 month later.

Participants/Inclusion and exclusion criteria

Patients who are a new case of HTN under treatment with losartan, age between 30-70, that has no comorbidity disease and no glaucoma and no eye diseases

Intervention groups

Intervention group: losartan systemic administration and measuring intraocular pressure in hypertensive patients before, one month, and three months after therapy.

Main outcome variables

Reduce intraocular pressure after losartan therapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210125050134N1**

Registration date: **2021-12-21, 1400/09/30**

Registration timing: **retrospective**

Last update: **2021-12-21, 1400/09/30**

Update count: **0**

Registration date

Registrant information

Name

Ali Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3445 2703

Email address

a_salehi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-23, 1400/04/02

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of onset of losartan systemic administration on intraocular pressure in hypertensive patients

Public title

Effect of losartan on intraocular pressure changes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

New HTN cases Monotherapy with losartan

Exclusion criteria:

Glaucoma Eye disease Comorbidity disease except HTN

Myopia and hyperopia

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **42**

More than 1 sample in each individual

Number of samples in each individual: **2**

Right eye, Left eye

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 Isfahan university of Medical Sciences

Street address

Feiz hospital, Modares St., Qhods sq.

City

Isfahan

Province

Isfahan

Postal code

۸۱۳۹۶۴۸۷۴

Approval date

2021-01-04, 1399/10/15

Ethics committee reference number

IR.MUI.MED.REC.1399.896

Health conditions studied

1

Description of health condition studied

Intraocular pressure changing in hypertensive patients with normal IOP

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intraocular pressure changing during 1 and 3 months

Timepoint

0 , 1month ,3months

Method of measurement

Tonometry , Goldman Slit Lamp Tonometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: tab. losartan 50mg administer daily for 3 month and follow up in single group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz hospital

Full name of responsible person

Afagh Ekramnia

Street address

Feiz hospital. Modares St. Ghods sq.

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Phone

+98 31 3446 7010

Email

afagh.ek@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo Javanmardi

Street address

Feiz hospital, Modares st, Ghods sq.

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Ali Salehi

Position

Associate Professor of Retina & Vitreous

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Ali Salehi

Position

Associate Professor of Retina and vitreous

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Afagh Ekramnia

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Phone

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available