

# 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.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

۸۱۳۹۶۴۸۷۴

##### 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.

##### City

Isfahan

##### Province

Isfahan

**Postal code**

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**Phone**

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**Email**

afagh.ek@gmail.com

**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 &amp; Vitreous

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ophthalmology

**Street address**

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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**

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Subspecialist

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**Email**

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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

**Street address**

Feiz hospital, Modares St., Gods sq.

**City**

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**Province**

Isfahan

**Postal code**

۸۱۴۹۶۴۴۸۷۴

**Phone**

+98 31 3446 7010

**Email**

afagh.ek@gmail.com

**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