

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The Effect of Topical Ketorolac on Diabetic Macular Edema

#### Protocol summary

##### Study aim

To determine the effect of topical ketorolac on diabetic macular edema

##### Design

This is a phase 3 clinical trial that is performed on 60 patients with diabetic macular edema.

##### Settings and conduct

This study is carried out at Kowsar Hospital in Sanandaj, Iran.

##### Participants/Inclusion and exclusion criteria

History of cataract surgery and vitrectomy, history of laser therapy of Avastin injection, HbA1C Instability, Sensitivity to the NSAIDs (NSAIDs or Aspirine-induced Asthma), Pregnancy, Severe retinopathy and active PDR, Retinal disorders (VR-traction,...)

##### Intervention groups

"intervention group": A group of patients who received the topical Ketorolac were considered as intervention group. "Control group": A group of patients who received the Artificial Tears were considered as control group.

##### Main outcome variables

Change in macular edema, change in visual activity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180114038350N2**

Registration date: **2018-09-25, 1397/07/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-09-25, 1397/07/03**

Update count: **0**

##### Registration date

2018-09-25, 1397/07/03

##### Registrant information

##### Name

Khaled Rahmani

##### Name of organization / entity

Kurdistan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3312 5880

##### Email address

khaledrahmani111@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-20, 1397/02/30

##### Expected recruitment end date

2018-12-30, 1397/10/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Topical Ketorolac on Diabetic Macular Edema

##### Public title

The Effect of Topical Ketorolac on Diabetic Macular Edema

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with Diabetic Macular Edema Age more than 18 years

##### Exclusion criteria:

History of cataract surgery and vitrectomy history of laser therapy of Avastin injection HbA1C Instability Sensitivity to the NSAIDs (NSAIDs or Aspirine-induced Asthma) Pregnancy Severe retinopathy and active PDR Retinal disorder( VR-traction,...)

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be conducted based on formation of permuted block randomization.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Since most of the outcomes in this study are objective outcomes and measured by standard devices, only patients will be blinded to receiving the drug.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Kurdistan University of Medical Sciences

**Street address**

Pasdaran Blvd. Kurdistan University Of Medical Sciences

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617713446

**Approval date**

2018-07-08, 1397/04/17

**Ethics committee reference number**

IR.MUK.REC.1396.297

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

Diabetic Macular Edema

**ICD-10 code**

E08.339

**ICD-10 code description**

Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema

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

Any changes in Macular Edema

**Timepoint**

Before intervention and one month after treatment initiation.

**Method of measurement**

Optical Coherence Tomography (OCT)

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

Any changes in visual Acuity

**Timepoint**

Before intervention and one month after treatment

**Method of measurement**

Snellen Chart

**Intervention groups****1****Description**

Intervention group: Group who receive Topical Ketorolac

**Category**

Treatment - Drugs

**2****Description**

Control group: Group who receive artificial tears

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Kawsar educational hospital

**Full name of responsible person**

Ghazal Kamali

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Dr.kamali.maryan@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Farzin Rezaei

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Kurdistan University of Medical Sciences, Sanandaj,  
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f.razaee@muk.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Sanandaj 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**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Khaled Rahmani

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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## Person responsible for scientific inquiries

#### Contact

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**Position**

Assistant professor

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Specialist

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## Person responsible for updating data

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

Yes - There is 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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

In case of publisher journal request, data would be sent to the journal.

**When the data will become available and for how long**

During the publication of paper and 6 months after publish

**To whom data/document is available**

Editor of the journal that publish the paper and academic researchers with permission of correspondence author

**Under which criteria data/document could be used**

Data can only used to meta analysis with permission of correspondence author

**From where data/document is obtainable**

The correspondence author of the study

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

By sending the mail to the correspondence author

**Comments**