# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**
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Khaled Rahmani
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**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 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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## Sponsors / Funding sources

**1**

**Sponsor**
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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**
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**
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Sanandaj University of Medical Sciences
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Assistant professor
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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**