

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### COMPARATIVE EVALUATION OF INTRAVITREAL DICLOFENAC PLUS BEVACIZUMAB VERSUS BEVACIZUMAB ALONE IN THE TREATMENT OF NAÏVE DIABETIC MACULAR EDEMA

#### Protocol summary

##### Study aim

To evaluate the therapeutic effects of intra-vitreous injection Bevacizumab combined with Diclofenac-Na versus intra-vitreous Bevacizumab alone in the treatment of naïve diabetic macular edema.

##### Design

Prospective, randomized, parallel group, interventional clinical practice trial

##### Settings and conduct

Eye dept. Nowshera Medical College/ Qazi Hussain Ahmad Medical Complex, Nowshera. The trial was non-blinded, prospective interventional study started from Sept. 2020 till March 2021.

##### Participants/Inclusion and exclusion criteria

The 'ETDRS' criteria was utilized for enrollment of treatment naïve eyes of DME, defined as any hard exudates/dot blot hemorrhages, retinal thickening/edema within 500µm from the center of the fovea or involving the very center, examined clinically on funduscopy Exclusions included: 1) Any history of prior retinal laser therapy 2) History of prior intravitreal injections any type (3) Any intra-ocular procedure done within last 6 months 4) Rubeosis irides 5) Any glaucomatous eye damage 6) evidence of ischemic maculopathy, defined as an enlarged foveal avascular zone (FAZ)  $\geq 1500\mu\text{m}$ ; 7) Best corrected VA of  $\geq 6/12$  or  $\leq 6/120$ ; 8) significant media opacity precluding fundus view 9) Associated morbid conditions like, monocular, pregnancy, diabetic nephropathy grade 3 and HbA1c  $\geq 10$ .

##### Intervention groups

INTRAVITREAL DICLOFENAC PLUS BEVACIZUMAB (IV-B/D) VERSUS BEVACIZUMAB (IV-B) ALONE

##### Main outcome variables

Primary outcome variable was Visual acuity in Log MAR Secondary outcome variable was Central sub-field thickness of Macula Tertiary variable was Intra-ocular

pressure (IOP)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220607055097N1**

Registration date: **2022-06-13, 1401/03/23**

Registration timing: **retrospective**

Last update: **2022-06-13, 1401/03/23**

Update count: **0**

##### Registration date

2022-06-13, 1401/03/23

##### Registrant information

##### Name

Adnan Ahmad

##### Name of organization / entity

Nowshera Medical College, Nowshera

##### Country

Pakistan

##### Phone

+92 91 2586506

##### Email address

dradnanahmad@hotmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-01, 1399/06/11

##### Expected recruitment end date

2021-03-30, 1400/01/10

##### Actual recruitment start date

2020-09-01, 1399/06/11

##### Actual recruitment end date

2021-03-30, 1400/01/10  
**Trial completion date**  
2021-10-04, 1400/07/12

**Scientific title**  
COMPARATIVE EVALUATION OF INTRAVITREAL DICLOFENAC PLUS BEVACIZUMAB VERSUS BEVACIZUMAB ALONE IN THE TREATMENT OF NAÏVE DIABETIC MACULAR EDEMA

**Public title**  
INTRAVITREAL DICLOFENAC PLUS BEVACIZUMAB VERSUS BEVACIZUMAB ALONE IN THE TREATMENT OF DIABETIC MACULAR EDEMA

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
The 'ETDRS' criteria was utilized for enrollment of treatment naïve eyes of DME, defined as any hard exudates/dot blot hemorrhages, retinal thickening/edema within 500µm from the center of the fovea or involving the very center, examined clinically on funduscopy Age range from 45 years to 78 years Type 2 DM  
**Exclusion criteria:**  
Any history of prior retinal laser therapy History of prior intravitreal injections any type Any intra-ocular procedure done within last 6 months Rubeosis irides Any glaucomatous eye damage evidence of ischemic maculopathy, defined as an enlarged foveal avascular zone (FAZ)  $\geq 1500\mu\text{m}$ ; Best corrected VA of  $\geq 6/12$  or  $\leq 6/120$  Significant media opacity precluding fundus view Associated morbid conditions like, monocularly, pregnancy, diabetic nephropathy grade 3 and HbA1c  $\geq 10$ .

**Age**  
From **45 years** old to **78 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **40**  
Actual sample size reached: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
1) Simple Randomization was done 2) Unit of randomization was taken an an individual 3) Computer software based randomization done 4) Allocation concealment was not done

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

None

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Institutional Ethical Review Board of Nowshera Medical College

##### Street address

Mardan road, near Kabul river, Nowshera

##### City

Nowshera

##### Postal code

24110

#### Approval date

2020-08-24, 1399/06/03

#### Ethics committee reference number

0386/R&D/IERB/NMC

## Health conditions studied

### 1

#### Description of health condition studied

Diabetic macular edema

#### ICD-10 code

E08.341

#### ICD-10 code description

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

## Primary outcomes

### 1

#### Description

Visual acuity improvement in Log MAR

#### Timepoint

Baseline, 4th, 12th and 24th week

#### Method of measurement

Visual acuity was measured with Snellen charts charts and than converted into Log. of minimum angle of resolution (Log MAR) units

## Secondary outcomes

### 1

#### Description

Central sub-field thickness of macula

#### Timepoint

Baseline, 4th, 12th and 24th week

#### Method of measurement

Macular thickness was measured in microns

## Intervention groups

1

### Description

Intervention group: Intravitreal Bevacizumab and Diclofenac (IV-B/D) Vs Intravitreal Bevacizumab alone (IV-B)

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Nowshera Medical College/ Qazi Hussain Ahmad Medical Complex

#### Full name of responsible person

Mubashir Rehman

#### Street address

Mardan road, near Kabul river, Nowshera

#### City

Nowshera

#### Postal code

24110

#### Phone

+92 923 9220325

#### Email

info@nmcn.edu.pk

#### Web page address

<https://nmcn.edu.pk/>

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Nowshera Medical College/ Qazi Hussain Ahmad Medical Complex

#### Full name of responsible person

Nizam Darwesh

#### Street address

Mardan road, near Kabul river, Nowshera

#### City

Nowshera

#### Postal code

24110

#### Phone

+92 923 9223025

#### Email

info@nmcn.edu.pk

#### Web page address

<https://nmcn.edu.pk/>

#### Grant name

None

#### Grant code / Reference number

None

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

Yes

### Title of funding source

Nowshera Medical College/ Qazi Hussain Ahmad Medical Complex

### 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

Nowshera Medical College

#### Full name of responsible person

Nizam Darwesh

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Community Eye research

#### Street address

Mardan road, near Kabul river, Nowshera

#### City

Nowshera

#### Province

Khyber Pukhtoonkhwa

#### Postal code

24110

#### Phone

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#### Email

drnizam@yahoo.co.uk

#### Web page address

<https://nmcn.edu.pk/>

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Nowshera Medical College

#### Full name of responsible person

Adnan Ahmad

#### Position

Assistant Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Cornea and Medical Retina

#### Street address

Civil colony, Kohat road

#### City

Peshawar

**Province**

Khyber Pukhtoonkhwa

**Postal code**

25000

**Phone**

+92 91 2586506

**Email**

dradnanahmad@hotmail.com

**Web page address**<https://nmcn.edu.pk/>**Person responsible for updating data****Contact****Name of organization / entity**

Nowshera Medical College

**Full name of responsible person**

Adnan Ahmad

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Ophthalmology

**Street address**

Civil colony, Kohat road

**City**

Peshawar

**Province**

Khyber Pukhtoonkhwa

**Postal code**

25000

**Phone**

+92 91 2586506

**Email**

dradnanahmad@hotmail.com

**Web page address**<https://nmcn.edu.pk/>**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Confidential

**Study Protocol**

Yes - There is 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**

Not applicable

**Data Dictionary**

Not applicable

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

1) IPD regarding Visual acuity in Log MAR 2) IPD regarding Macular thickness in microns

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

Data is available

**To whom data/document is available**

People working in Academic Institutions

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

For conducting further research in this field to explore more knowledge

**From where data/document is obtainable**

Dr. Adnan Ahmad, dradnanahmad@hotmail.com, 0092 3339121281, Cemcon House, Civil colony, Kohat road, Peshawar, KPK, Pakistan

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

Request an application for data access/ document via an email

**Comments**

Feel free to ask for any query