

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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 ≥ 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
fundoscopy 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 ≥ 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

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Nowshera

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24110

Phone

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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

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Email

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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

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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

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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

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Latest degree

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Other areas of specialty/work

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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