Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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-vitreal injection Bevacizumab combined with Diclofenac-Na versus intra-vitreal 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 fundoscopy 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) ≥ 1500µm; 7) Best corrected VA of ≥ 6/12 or ≤ 6/120; 8) significant media opacity precluding fundus view 9) Associated morbid conditions like, monocularity, 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
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+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) ≥ 1500µm; Best corrected VA of ≥ 6/12 or ≤ 6/120 Significant media opacity precluding fundus view Associated morbid conditions like, monocularity, 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
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Mardan road, near Kabul river, Nowshera
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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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