

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the Efficacy of Diclofenac 0.1% and Nepafenac 0.1% on anterior chamber cells in patients Undergoing Cataract Surgery: a Prospective clinical practice trial

#### Protocol summary

##### Study aim

: To compare the efficacy of topical nepafenac 0.1 % and diclofenac 0.1% eye drops in reducing the aqueous cells in the anterior chamber in an uneventful post cataract surgery.

##### Design

Sample size= 70 patients, Probability sampling by simple randomization (via computer-generated no.), parallel-group, non-blind, clinical practice trial

##### Settings and conduct

The study was conducted an an Eye dept. of Nowshera Medical College

##### Participants/Inclusion and exclusion criteria

Patients'  $\geq$  50 yrs. Both males and females with visually significant senile-cataracts under-going phaco-emulsification with intra-ocular lens implantation were enrolled. Exclusion criteria were any past intra-ocular surgery, any history of any intra-ocular inflammatory diseases, traumatic globe injuries, corneal disorders impairing the view, any glaucomatous diseases of eye, pseudo-exfoliation, any retinal/macular abnormalities, such as macular edema due to other etiologies or epiretinal membranes or any age-related maculopathy. Those not willing to follow the study protocols and requirements of follow up were also excluded. Those who were pre-diabetics and confirmed diabetics, with systemic autoimmune/inflammatory disorders or any history of allergic reaction to the study drugs or other NSAIDs were also expelled. Oral steroids or NSAIDs intake was prohibited for the participants throughout the trial duration. Patients with eventful phaco surgery such as posterior-capsular tear, vitreous-prolapse or post-operative fibrinous reactions were not recruited for the study.

##### Intervention groups

Topical Diclofenac 0.1% (TD) Topical Nepafenac 0.1% (TN)

##### Main outcome variables

BCVA (visual acuity) converted into Log MAR; CMT measured in microns by SD-OCT; Mean AC cells

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220607055097N2**

Registration date: **2022-07-05, 1401/04/14**

Registration timing: **retrospective**

Last update: **2022-07-05, 1401/04/14**

Update count: **0**

##### Registration date

2022-07-05, 1401/04/14

##### 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

2021-01-01, 1399/10/12

##### Expected recruitment end date

2021-12-31, 1400/10/10

##### Actual recruitment start date

2021-01-01, 1399/10/12  
**Actual recruitment end date**  
2021-12-31, 1400/10/10  
**Trial completion date**  
2022-01-30, 1400/11/10

**Scientific title**

Comparison of the Efficacy of Diclofenac 0.1% and Nepafenac 0.1% on anterior chamber cells in patients Undergoing Cataract Surgery: a Prospective clinical practice trial

**Public title**

Effect of Diclofenac 0.1% Vs. Nepafenac 0.1% on anterior chamber reaction in post-operative (cataract) cases.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients' ≥ 50 yrs. Both males and females with visually significant senile-cataracts under-going phacoemulsification with intra-ocular lens implantation

**Exclusion criteria:**

Any past intra-ocular surgery Any history of any intra-ocular inflammatory diseases, Traumatic globe injuries Corneal disorders impairing the view Any glaucomatous diseases of eye Pseudo-exfoliation cataracts any retinal/macular abnormalities, such as macular edema due to other etiologies or epi-retinal membranes or any age-related maculopathy. Those not willing to follow the study protocols and requirements of follow up Those who were pre-diabetics and confirmed diabetics Those with systemic autoimmune/inflammatory disorders or any history of allergic reaction to the study drugs or other NSAIDs Patients with eventful phaco surgery such as posterior-capsular tear, vitreous-prolapse or post-operative fibrinous reactions

**Age**

From **50 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

Actual sample size reached: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Method= Simple randomization, Unit= Individual, Tool= computer software, Random sequence created via computer software, allocation concealment not done

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Prospective, randomized clinical practice trial

**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**

2021-01-01, 1399/10/12

**Ethics committee reference number**

NO: 0337 /R&D/IERB/NMC

**Health conditions studied**

1

**Description of health condition studied**

Anterior chamber reaction inside the eye after cataract surgery

**ICD-10 code**

H59.039

**ICD-10 code description**

Cystoid macular edema following cataract surgery, unspecified eye

**Primary outcomes**

1

**Description**

BCVA (visual acuity) in Log MAR

**Timepoint**

Baseline, 1st day, 2nd, 4th and 8th week

**Method of measurement**

VA measured with Snellen chart and than converted into Logarithm of minimum angle of resolution

2

**Description**

Anterior chamber cells

**Timepoint**

Baseline, 1st day, 2nd, 4th and 8th week

**Method of measurement**

Slit lamp examination method by counting the no. of cells in anterior chamber of eye

### 3

**Description**

Central macular thickness

**Timepoint**

Baseline, 1st day, 2nd, 4th and 8th week

**Method of measurement**

Central macular thickness was measured in microns by SD-OCT

**Secondary outcomes**

empty

**Intervention groups**

### 1

**Description**

Intervention group: Topical Diclofenac 0.1% eye drops (TD), used 4 times/day for 4 weeks in the operated eyes

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group: Topical Nepafenac 0.1% (TN) eye drops, used 3 times/day for 4 weeks in the operated eyes

**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

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**Phone**

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drmubashirrehman78@gmail.com

**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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**Phone**

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**Web page address**

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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**

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, Nowshera

**Full name of responsible person**

Adnan Ahmad

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Ophthalmology

**Street address**

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**Province**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Nowshera Medical College, Nowshera

**Full name of responsible person**

Adnan Ahmad

**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Ophthalmology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Nowshera Medical College, Nowshera

**Full name of responsible person**

Adnan Ahmad

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Ophthalmology

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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**

No - There is not 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**

All collected

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

3 months after publication till 1 year post publication

**To whom data/document is available**

Academic institutions

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

For research purposes

**From where data/document is obtainable**

Via emails upon request

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

By sending request via email and purpose of needing the data/documents

**Comments**

feel free to ask for any queries