

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Postal code

24110

Phone

+92 923 9220325

Email

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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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

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Civil colony

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Person responsible for scientific inquiries

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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

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Person responsible for updating data

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Position

Assistant Professor

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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