Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 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' ≥ 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 epi-retinal 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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24110
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drmubashirrehman78@gmail.com
Web page address
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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
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Phone
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Email
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Web page address
https://nmcn.edu.pk/
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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Position
Assistant Professor

Latest degree
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Person responsible for updating data

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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