Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the effect of indomethacin as a non-steroidal anti-inflammatory drug and acetaminophen for postoperative pain in patients undergoing cross-linking (cxl) surgery

Protocol summary

Study aim

The aim of this study was to compare the effect of using a single dose of indomethacin 75 mg non-steroidal anti-inflammatory drug (SIDS) and a single dose of 500 mg acetaminophen tablets on postoperative pain in patients referred to Shahid Sadoughi Hospital in Yazd for collagen cross-linking surgery. Will be done

Design

The present study is a clinical trial with a control group, with a parallel group, double-blind, randomized on 50 patients and divided into two groups using a table of random numbers.

Settings and conduct

It is performed in Shahid Sadoughi Hospital in Yazd. Group A receives indomethacin tablets before surgery and group B receives 500 mg acetaminophen tablets. It is given from surgery and the researcher's colleague is aware of which drugs A and B are included. Using the Visual Aid Scale Questionnaire and the number of analgesics used during the 24 hours after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria included male and female patients between 16 and 35 years of age, including unlikely consecutive sampling of significant keratoconus with reading k greater than 47D and central corneal thickness greater than um400.Exclusion criteria for people with a history of eye surgery, acute corneal hydrops, dense corneal ectasia, corneal opacity, any history of NSAID allergies, or the use of topical / systemic anti-inflammatory drugs are excluded within two weeks prior to surgery. Also, patients with a BMI of less than 18.5 and more than 30 are excluded from the study due to changes in the use of analgesic doses for pharmacological effects.

Intervention groups

In this study, patients are divided into groups A and B. Group A receives 75 mg of slow-release indomethacin tablets one hour before surgery and group B receives 500 mg of acetaminophen tablets one hour before surgery.

Main outcome variables

The effect of anti-inflammatory drugs, the amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211215053417N1**
Registration date: **2021-12-20, 1400/09/29**
Registration timing: **prospective**

Last update: **2021-12-20, 1400/09/29**
Update count: **0**

Registration date

2021-12-20, 1400/09/29

Registrant information

Name

faezeh mazidi sharafabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3830 2343

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-25, 1400/10/04

Expected recruitment end date

2022-01-24, 1400/11/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of indomethacin as a non-steroidal anti-inflammatory drug and acetaminophen for postoperative pain in patients undergoing cross-linking (cxl) surgery

Public title

Comparison of the effect of indomethacin as a non-steroidal anti-inflammatory drug and acetaminophen for postoperative pain in patients undergoing cross-linking (cxl) surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male and female patients between 16 and 35 years of age included unlikely consecutive sampling of significant keratoconus with readings greater than 47 d and central corneal thickness greater than 400um.

Exclusion criteria:

patients with a history of eye surgery, acute corneal hydrops, dense corneal ectasia, corneal opacity, any history of NSAID allergies, or the use of topical / systemic anti-inflammatory drugs are excluded from the study within two weeks prior to surgery. Also, patients with a BMI of less than 18.5 and more than 30 are excluded from the study due to changes in the use of analgesic doses for pharmacological effects.

Age

From **16 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind clinical trial. The aim of comparing the effect of using a single dose of non-steroidal anti-inflammatory drug indomethacin 75 mg slow release and a single dose of acetaminophen 500 mg on postoperative pain in patients referred to Shahid Sadoughi Hospital in Yazd for collagen cross-linking surgery will be done. This study is a double-blind clinical trial in which two drugs are given to a patient before surgery in bottles labeled with drugs A and B by a research colleague And the research partner is aware of what drugs A and B contain. Also, before surgery, the patient is explained that the judgment used for this study is a single dose of 75 mg slow-release indomethacin tablets or a single dose of 500 mg acetaminophen tablets, but the patient does not know which of these two drugs to take before surgery. Uses. It should be noted that these two drugs are similar in form and the patient is not able to distinguish between the two drugs in terms of appearance.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of yazd University of Medical Sciences

Street address

Bahonar Square, University Headquarters, Vice Chancellor for Research and Technology

City

Yazd

Province

Yazd

Postal code

9417612345

Approval date

2021-12-20, 1400/09/29

Ethics committee reference number

IR.SSU.SPH.REC.1400.122

Health conditions studied

1

Description of health condition studied

cross-linking (cxl) surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Visual Pain Scale (VAS) Score

Timepoint

Visual Pain Scale (VAS) questionnaire is determined at 4 hours after surgery and the number of analgesics used

during 24 hours after surgery.

Method of measurement

Visual Pain Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One hour before surgery, they receive a single dose of 75 mg slow-release indomethacin tablets made in Iran and Aria Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Control group: One hour before surgery, they receive a single dose of 500 mg acetaminophen tablets, which are made in Iran and Shafa Pharmaceutical Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Faezeh Mazidi Sharafabadi

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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

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd University of Medical Sciences

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

Yazd University of Medical Sciences

Full name of responsible person

Faezeh Mazidi Sharafabadi

Position

Masters student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available