

# Comparing the Efficacy and Safety of Indomethacin 0.1% Eyedrops versus Ketorolac 0.5% Eyedrops in Ocular Inflammation After Cataract Surgery

|                   |                      |  |
|-------------------|----------------------|--|
| Submission date   | Recruitment status   | <input type="checkbox"/> Prospectively registered    |
| 03/03/2010        | No longer recruiting | <input type="checkbox"/> Protocol                    |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan   |
| 25/03/2010        | Completed            | <input type="checkbox"/> Results                     |
| Last Edited       | Condition category   | <input type="checkbox"/> Individual participant data |
| 31/03/2010        | Eye Diseases         | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Michel Weber

### Contact details

Service d'Ophthalmologie  
Hotel Dieu CHU de Nantes  
1 place Alexis Ricordeau  
Nantes  
France  
44093

## Additional identifiers

### Protocol serial number

# 539

## Study information

### Scientific Title

# A Multicentre, Investigator-Masked, ParallelGroup, Randomized, Study of the Efficacy and Safety of Indomethacin 0.1% Eyedrops Compared with Ketorolac 0.5% Eyedrops in Ocular Inflammation After Cataract Surgery

## Acronym

Indocollyr Study

## Study objectives

A treatment with indomethacin 0.1% is non-inferior to a treatment with ketorolac 0.5% in the prevention of ocular inflammation following cataract surgery.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. France (Lead Centre): Local Ethics Committee (Comité de Protection des Personnes [CPP] Tours, Ouest-1) approved on the 8th of February 2008 (ref: 2007-004686-18)
2. Poland: Local Ethics Committee (Komisja Bioetyczna, Akademia Medyczna) approved on the 31st of March 2008 (ref: KE-0254/58/2008)
3. Portugal: Local Ethics Committee (Comissao de Etica para a Investigacao Clínica [CEIC], Parque da Saúda de Lisboa) approved on the 14th of April 2008 (ref: CEIC 07128BU598)
4. Germany: Local Ethics Committee (Ärztekammer des Saarlandes, Ethikkommission) approved on the 25th of September 2008 (ref: Sn 148/08)

Potential subjects who meet eligibility requirements will be scheduled for 6 study visits over a period of approximately 90 days. Subjects who meet eligibility requirements will be randomized (1:1) to receive test (indomethacin 0.1%) or active-control (ketorolac 0.5%) in the study eye. Study eyes will receive 1 drop of study drug, four times daily, for 3 weeks.

## Study design

Multicentre investigator blinded randomised active controlled parallel group trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Cataract; surgery; phacoemulsification

## Interventions

Potential subjects who meet eligibility requirements will be scheduled for 6 study visits over a period of approximately 90 days. Subjects will be randomized (1:1) to receive test (indomethacin 0.1%) or active-control (ketorolac 0.5%) in the study eye. Study eyes will receive 1 drop of study drug, four times daily, for 3 weeks.

The test article is commercially available with different brand names in the countries where the study takes place. It is manufactured by Bausch & Lomb, Chauvin, Montpellier, France and contains indomethacin ophthalmic solution 0.1%, preserved with thiomersal (10 mg/100 ml).

The active control is commercially available Acular, marketed by Allergan Incorporated in France. Acular contains ketorolac tromethamine 0.5% and is preserved with benzalkonium chloride 0.01%.

## Intervention Type

Other

## Phase

Phase IV

## Primary outcome(s)

The primary efficacy endpoint is aqueous flare, measured with an LFM, at Day 1 and Day 7 after cataract surgery

## Key secondary outcome(s)

1. Aqueous flare, measured with an LFM, at Day 30 and Day 90 after cataract surgery
2. Change from baseline in retinal thickness measured with an Optical Coherence Tomograph at Day 30 and Day 90
3. Anterior chamber flare and cells, as well as conjunctival hyperaemia and perikeratic circle, measured through slit lamp examinations
- Post surgical pain/discomfort immediately after surgery (Day 0) and 24 hours after surgery (Day 1)
4. Change from baseline in the appearance of the macula and the rest of the retina, assessed through dilated, indirect funduscopy at Day 30 and Day 90
5. Use of concomitant medications to treat inflammation related to cataract surgery at each visit

The safety endpoints include the following:

6. Corneal epithelial erosions at Day 7 and Day 30 measured with fluorescein strips and a cobalt filter on a slit lamp
7. Subjective tolerance to study drug upon instillation at Day 0 (prior to surgery), Day 7, and retrospective evaluation at Day 30
8. Best-corrected distance visual acuity (BCDVA) at Day 7, Day 30, and Day 90
9. Change from baseline in IOP at Day 7, Day 30, and Day 90
10. Adverse Events

## Completion date

17/09/2009

## Eligibility

### Key inclusion criteria

Subjects must be of legal age (at least 18) and have full legal capacity to volunteer.

2. Subjects must read, understand, and sign the Institutional Review Board/Independent Ethics Committee approved Informed Consent Form.
3. Subjects must be planning to undergo cataract surgery on one eye by phacoemulsification with posterior chamber intraocular lens, using topical anaesthesia.
4. Subjects must have a preoperative flare  $\leq 15$  ph/ms, measured with a laser flare meter (LFM) without pharmacological pupil dilation, within the 2 months preoperatively.
5. Subjects who are women of childbearing potential must have a negative urine

pregnancy test at baseline.

6. Subjects who are able and willing to comply with all treatment and follow-up procedures

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Subjects who have an inflammatory and/or infectious pathology of the eye and its adnexa
2. Subjects who have a history of postoperative intraocular infection in the fellow eye
3. Subjects who have glaucoma in the study eye
4. Subjects who have post-traumatic cataract in the study eye
5. Subjects who have exfoliative syndrome
6. Subjects who have diabetes
7. Subjects who have an active peptic ulcer
8. Subjects who have severe hepatocellular impairment or severe renal impairment
9. Subjects who have a history of uveitis
10. Subjects who have any progressive pathology requiring the use of topical or systemic anti-inflammatory or anti-infectious agents
11. Subjects who take acetylsalicylic acid at doses > 100 mg daily and cannot discontinue usage during the study
12. Subjects who have a history of asthma linked to acetylsalicylic acid or other nonsteroidal anti-inflammatory (NSAI) drug administration
13. Subjects with immunodepression
14. Subjects with a history of intolerance to the study drug or to any NSAI drug
15. Subjects who are monocular for any reason other than cataract
16. Subjects who are treated with local or systemic anti-inflammatory drugs within 10 days prior to inclusion
17. In the case of cataract surgery on the 2nd eye, if the subject was already included in the study for the 1st eye, the 2nd eye cannot be considered another study eye.
18. Subjects who have surgery planned to occur during the course of the study other than cataract surgery on the study eye or cataract surgery on the fellow eye. If cataract surgery is planned to occur for the fellow eye before Visit 5 (Day 30,  $\pm 3$  days) is completed, the subject must be excluded.
19. Women who are pregnant or breastfeeding
20. Women who are sexually active and who do not fall into one of the following categories:
  - 20.1. Post menopausal
  - 20.2. Surgically sterile

20.3. Using one of the following birth control methods throughout the duration of the study:

20.3.1. Intrauterine device (>14 days)

20.3.2. Barrier method (condom or diaphragm) with spermicide (>14 days)

20.3.3. Hormonal contraception (same dose and same formulation for at least six months)

Secondary criteria for exclusion from the efficacy analysis include perioperative complications (i.e., vitreous loss, complicated capsular rupture, and anterior chamber intraocular lens) which will also be considered adverse events (AEs)

#### **Date of first enrolment**

08/04/2008

#### **Date of final enrolment**

17/09/2009

## **Locations**

#### **Countries of recruitment**

France

Germany

Poland

Portugal

#### **Study participating centre**

Service d'Ophthalmologie

Nantes

France

44093

## **Sponsor information**

#### **Organisation**

Dr. Mann Pharma GmbH, Bausch & Lomb Inc. (Germany)

#### **ROR**

<https://ror.org/049ncrn81>

## **Funder(s)**

#### **Funder type**

Industry

**Funder Name**

Bausch & Lomb GmbH (Germany)

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

| Output type  | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|--|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#"><u>Participant information sheet</u></a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |