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

Submission date 03/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/03/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 31/03/2010	**Condition category** Eye Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available

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

Secondary outcome measures
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

Overall study start date
08/04/2008

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 ≤ 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

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, ±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 dOphthalmologie
Nantes
France
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Sponsor information

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

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Sponsor type
Industry

ROR
https://ror.org/049ncrn81

Funder(s)

Funder type
Industry

Funder Name
Bausch & Lomb GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration