Clinical Evaluation of Nepafenac Ophthalmic Suspension, 0.3% for Prevention and Treatment of Ocular Inflammation and Pain after Cataract Surgery

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The objectives of this study are to demonstrate that Nepafenac Ophthalmic Suspension, 0.3% is not inferior to Nepafenac Ophthalmic Suspension, 0.1% (NEVANAC®); Nepafenac Ophthalmic Suspension, 0.3% is superior to Nepafenac 0.3% Vehicle and NEVANAC...

Ethical review	Not approved
Status	Will not start
Health condition type	Eye disorders
Study type	Interventional

Summary

ID

NL-OMON34348

Source
ToetsingOnline

Brief title
Confirmatory Study Nepafenac 0.3%

Condition

- Eye disorders

Synonym
ocular inflammation and pain after cataract surgery

Research involving
Human

Sponsors and support

Primary sponsor: Alcon Laboratories
Source(s) of monetary or material Support: Alcon Laboratories

Intervention

Keyword: Nepafenac, Nevanac®

Outcome measures

Primary outcome

The proportion of patients with clinical cure at day 14. Clinical cure is

defined as a score of 0 for both aqueous cells and flare.

Secondary outcome

The proportion of patients who are pain-free as assessed by the Investigator at

day 14. Pain-free is defined as a score of 0 on the Investigator rating scale

which ranges from 0 (none) to 5 (severe).

Study description

Background summary

The purpose of this research study is to evaluate the safety and effectiveness of an investigational NSAID eye drop, Nepafenac Ophthalmic Suspension 0.3% for the prevention and treatment of pain and inflammation associated with cataract surgery.

Study objective

The objectives of this study are to demonstrate that Nepafenac Ophthalmic Suspension, 0.3% is not inferior to Nepafenac Ophthalmic Suspension, 0.1% (NEVANAC®); Nepafenac Ophthalmic Suspension, 0.3% is superior to Nepafenac 0.3% Vehicle and NEVANAC is superior to NEVANAC Vehicle for the prevention and treatment of ocular pain and inflammation following cataract surgery.

Study design

Parallel, Multi-center, Double-masked, Active and Vehicle controlled four-arm study:
* Nepafenac Ophthalmic Suspension, 0.3% dosed once daily
* NEVANAC dosed three times daily
* Nepafenac 0.3% Vehicle dosed once daily
* NEVANAC Vehicle dosed three times daily

Number of Centers: Up to 85 sites in US and EU
Number of Patients: Estimated 24 patients per site.
Total: approximately 2000 patients enrolled (800 per active treatment group who will either receive Nepafenac Ophthalmic Suspension, 0.3% or NEVANAC; 200 per Vehicle group who will either receive Nepafenac 0.3% Vehicle or NEVANAC Vehicle)

Duration of Treatment: 16 days (dosing will start one day before surgery, on the day of surgery [an additional dose will be instilled 30-120 minutes prior to surgery] and 14 days following surgery day)

Intervention

Not applicable

Study burden and risks

The patient will be assigned by chance, through a procedure similar to tossing a coin, to receive one of the following study eye drop treatment groups. The chance of being assigned to one of the two Placebo groups is approximately 20% (or 1 out of 5 patients). The chance of being assigned to one of the two active groups is approximately 80% (or 4 out of 5 patients).

1) Nepafenac Ophthalmic Suspension, 0.3%. One eye drop administered once daily
2) Nepafenac 0.3% Vehicle (Placebo) One eye drop administered once daily
3) NEVANAC One eye drop administered three times daily.
4) NEVANAC Vehicle (Placebo) One eye drop administered three times daily.

For the eye examination, the pupils will be dilated (enlarged). Dilation of the pupil may cause light sensitivity and slight blurring of vision for up to 4 hours after testing. Wearing sunglasses for several hours after dilation can help reduce the discomfort of light sensitivity. Also, driving may be difficult so it is advisable to arrange for transportation home.

The eye pressure test involves the placement of eye drops containing a small amount of a numbing drop into the eye. It is important that the patient does not rub the eyes for at least fifteen (15) minutes after the drops are put in the eye, since small particles or dust in the eye might scratch the cornea and the numbing drop would make the patient temporarily unable to feel the pain.

Minor scratching of the corneal surface may rarely occur when the pressure in the eye is measured.

The use of Nepafenac Ophthalmic Suspension, 0.3% or NEVANAC during intraocular surgery may not decrease the chance of inflammation. If the patient is in the treatment group that receives placebo (inactive ingredient) the symptoms or condition may worsen or not improve.
The investigator will carefully monitor the patient after surgery and will prescribe additional medication if the inflammation associated with the eye is above an expected level.

The possible benefit the patient may experience from the investigational use of Nepafenac Ophthalmic Suspension, 0.3% and NEVANAC may be a reduction in the amount of eye inflammation after cataract surgery. Participating in this study may benefit the patient by reducing the amount of eye inflammation and pain after cataract surgery. This may result in a faster recovery of vision following surgery. Additionally, the participation in a controlled clinical study helps to advance the understanding of how this type of medicine may prevent or reduce inflammation at the back of the eye after cataract surgery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Men or women of any race, 18 years or older who have cataract, and are planning to undergo cataract extraction by phacoemulsification with the implantation of a posterior chamber intraocular lens
2. Study eye of patients who in the opinion of the investigator will have improvement in best-corrected visual acuity after surgery
3. Patients should be able to understand and sign an informed consent that has been approved by an
Institutional Review Board/Independent Ethics Committee. Note: Legally authorized representative of the patient can provide informed consent

Exclusion criteria

1. Planned multiple procedures during cataract/IOL implantation surgery (eg. trabeculectomy, corneal transplant). Note: A planned limbal relaxing incision may be performed for the correction of astigmatism
2. Use of topical, topical ocular, inhaled or systemic nonsteroidal anti-inflammatory drugs within 7 days of surgery, with the exception of the allowed low dose of aspirin (up to 100 mg) prior to surgery and through study exit
3. Use of topical, topical ocular, inhaled or systemic steroids within 14 days prior to surgery and through
study exit
4. Use of a topical ophthalmic prostaglandin in the operative eye (eg travoprost, latanoprost, bimatoprost, tafluprost). Patients with a previous history of topical ophthalmic prostaglandin use must discontinue at least 4 days prior to surgery and through study exit
5. Any intraocular inflammation (aqueous cells or flare greater than Grade 0) or ocular pain greater
than Grade 1 in the study eye that is present during the Baseline visit
6. Previous ocular trauma to the operative eye (this includes cataract and previous intraocular
surgery, where a wound is created to gain access to the anterior or posterior segments; this does not include previous laser therapy without use of an incision)
7. A history of chronic or recurrent inflammatory eye disease (eg, iritis, scleritis, uveitis, iridocyclitis, rubeosis iridis) in the operative eye
8. Patients who in the opinion of the investigator are at increased risk of developing postoperative

macular edema (eg. diabetic retinopathy) in the operative eye
9. Currently diagnosed uncontrolled glaucoma in the operative eye
10. Lens pseudoexfoliation syndrome with glaucoma or zonular compromise in the operative eye
11. Congenital ocular anomaly (eg, aniridia, congenital cataract) in the operative eye
12. A visually nonfunctional fellow eye defined as a best-corrected visual acuity * 35 ETDRS letters (20/200 Snellen equivalent) or worse
13. Participation in any other investigational drug or device study within 30 days before cataract surgery
14. Known or suspected allergy or hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs), or to any component of the test article
15. Women of childbearing potential (those who are not surgically sterilized or post menopausal)
may not participate in the study if any of the following conditions exist:
a. they are breast-feeding;
b. they have a positive urine pregnancy test at screening;
c. they are not willing to undergo a urine pregnancy test upon entering or exiting the study;
d. they intend to become pregnant during the duration of the study; or,
e. they do not agree to use adequate birth control methods for the duration of the study (adequate birth control methods are: hormonal - oral, implantable, or injectable contraceptives; mechanical - spermicide in conjunction with a barrier such as condom or diaphragm; IUD; or, surgical sterilization of partner)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	120

Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Nepafenac Ophthalmic Suspension 0,3%
Generic name:	Nepafenac Ophthalmic Suspension 0,3%
Product type:	Medicine
Brand name:	Nepafenac Ophthalmic Suspension 0.1%.
Generic name:	NEVANAC®
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-08-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-10-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-11-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Not approved Date:	21-01-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2010-019507-28-NL
ClinicalTrials.gov	NCT01109173
CCMO	NL32931.078.10