Study of the Safety and Efficacy of Anercortave Acetate for Treatment of Steroid Induced IOP Elevation

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The primary objective of the study is to evaluate the safety and efficacy of Anecortave Acetate Depot (3, 15 or 30 mg) when administered by AJD for treatment of elevated IOP following intravitreal steroid therapy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Eye disorders NEC
Study type	Interventional

Summary

ID

NL-OMON30214

Source
ToetsingOnline

Brief title
Anecortave Acetate for Treatment of Steroid Induced IOP Elevation

Condition

- Eye disorders NEC

Synonym
ocular hypertension; increased pressure inside the eye

Research involving
Human

Sponsors and support

Primary sponsor: ALCON/LABORATORIES
Source(s) of monetary or material Support: ALCON LABORATORIES

Intervention

Keyword: Anecortave Acetate, Anterior Juxtascleral depot (AJD), IOP Elevation, Steroid Induced

Outcome measures

Primary outcome

The primary efficacy endpoint will be the mean change in IOP (mmHg) from

baseline to Week 4. Comparisons between the different treatment groups (3 mg,

15 mg and 3O mg) and placebo will be made.

Secondary outcome

Secondary parameters will include the time to treatment failure and the

pencentage of patients declared to be treatment failures.

A target IOP will be established by the investigator. Patients for whom the

IOP in the study eye exceeds the target IOP at Week 4, will come for an

additional IOP measurement one week later. In case the target IOP is still

exceeded, the patient is considered a treatment failure.

Study description

Background summary

locally administered glucocorticoids are commonly used to treat noninfectious inflammation of the eye. Glucocorticoids have the ability to suppress the inflammatory response including cellular infiltration, redness and swelling. Intravitreal injection is becoming more frequently employed for patients with macular edema. This type of therapy has undesirable side effects however, including the tendency to raise intraocular pressure (IOP) in certain individuals. Depending on the potency of the steroid, IOP elevation can develop within a few weeks or in months. Between 30 to 40% of the general population responds with moderate to severe increases of IOP when treated with intravitreal steroids (like triamcinolone acetonide). This increase requires a treatment with topical ocular hypotensive therapy. If this therapy is not

adequate, surgery is required. Anecortave acetate, administered as a anterior juxtascleral depot (AJD) may provide an alternative to these approaches.

Anecortave acetate belongs to a unique class of drugs, cortisenes, which have IOP lowering ability as well as angiostatic activity. The IOP lowering activity is believed to be due to the normalization of glucocorticoid-induced changes in the trabecular meshwork, thus increasing aqueous humor outflow.

Study objective

The primary objective of the study is to evaluate the safety and efficacy of Anecortave Acetate Depot (3, 15 or 30 mg) when administered by AJD for treatment of elevated IOP following intravitreal steroid therapy.

Study design

This study is a randomized, controlled, double-masked study in which three treatment groups are compared with placebo.
During the baseline exam, a complete ophthalmic exam will be performed and the investigator will establish the target IOP, which the patient should meet following administration of Anecortave Acetate. During the study, the study eye will be frequently checked and in case the target IOP is not met at Week 4, the patient is considered as a treatment failure and additional hypotensive therapy will be started.

Intervention

Every patient who complies with the in- and exclusion criteria, will get one injection of Anecortave Acetate (3, 15 or 30 mg or placebo) via the AJD procedure.

Study burden and risks

A burden to the patients can be the frequent follow up visits (Week 1, Week 2, Week 4, Week 6, Month 3, Month 4.5 and Month 6).
The following adverse events have been reported in patients who received Anecortave Acetate via the PJD procedure (posterior juxtascleral depot). The expectation is that the safety profile will not be different in this study.
The study medication could cause all, some or none of the mentioned complaints: at the injection site: pain, bleeding, scarring, ; ocular pain, decrease of vision, feeling of discomfort, itchy eye, red eyes, ptosis of upper eyelid, swelling of eyelids.
Most of the possible effects above may be caused by the injection itself but are not serious and none will last. However, these effects may be seen in the placebo group. Other effects, such as cataract and decreased vision, may also

be due to aging.

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

patients of either sex and any race/ethnicity, 18 years of age or older.
Patient that have received intravitreal steroid therapy.
Patients between 2 and 8 week (14 to 56 days) post-intravitreal steroid therapy with an IOP of at least 24 mmHg and who have an IOP increase > 10 mmHg relative to their pre-steroid therapy in a single eye.
NOTE: only one eye per patient may be enrolled in the study.
Only patients who satisfy all informed consent requirements may be included in the study.
Patient with at least 30 days of stable dosing of ocular hupotensive medications prior to screening may be included.

Patients using nonprescription and/or prescription topical ophthalmic and/or systemic non-glaucoma medications may be included in the study.
Patients who wear contact lenses will be allowed to participate in the study provided that they are willing to discontinue use during the course of the study.

Exclusion criteria

Patients on intravenous or subcutaneous anticoagulant therapy, or patient on oral anticoagulant therapy and cannot take a 5-day interruption in therapy prior to each injection procedure (with exception of aspirin and antiplatelet therapy).
Patients who are currently on therapy or were on therapy with another investigational agent within 30 days prior to screening.
Patients who are currently on therapy or were on therapy with systemic glucocorticoid medications within 30 days prior to Screening Visit.
Patients who have a known medical history of allergy to the steroid family of drugs.
History of ocular trauma wihin the past six months in the study eye (eye to be treated).
Patient with a history of penetrating glaucoma surgery (i.e. trabeculectomy, valves, etc.) in the study eye.
Patient has had an insertion of scleral buckle in the study eye.
Patients with a cup/disc ratio greater than 0.80 (horizontal or vertical measurement) in either eye.
Any abnormality preventing reliable applanation tonometry of the study eye.
Patients with clinical evidence of scleral thinning seen at the time of external eye examination or at the time of administration.
History or other evidence of severe illness or any other condition which would make the patient, in the opinion of the Investigator, unsuitable for the study.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	6
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Retaane
Generic name:	Anecortave Acetate

Ethics review

Approved WMO Date:	02-10-2006
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-06-2007
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-11-2007
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2006-003356-38-NL
CCMO	NL14539.091.06