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OCTOME study

Submission date
11/06/2011

Recruitment status
No longer recruiting

Registration date
29/06/2011

Overall study status
Completed

Last Edited
18/03/2016

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Macular oedema is the most common cause of visual impairment in retinal vascular diseases (diseases affecting the blood vessels of the eyes). Ozurdex is a biodegradable implant injected into the eye and containing a medication called dexamethasone. The implant is slowly dissolved in the eye, releasing the drug. It has been tested in other studies based on 6 monthly dosing but the results indicated that the effect of the drug may wear off earlier. The aim of this project was to monitor the visual acuity (how clear the vision is) and macular thickness (thickness of an oval-shaped pigmented area near the retina of the eye) every month to determine at which point the dosing of Ozurdex provides the maximal effect and correlate structural changes (of the eye) with visual acuity.

Who can participate?
Adults with macular oedema.

What does the study involve?
All participants are treated with Ozurdex and the their progress followed up every 4 weeks for the next 36 weeks. If sufficient progress has not been made (for example, if macular thickness has not increased sufficiently) one extra treatment is allowed between weeks 16 and 24.

What are the possible benefits and risks of participating?
Participants may benefoit from successful treatment of their macular oedema. Potential risks include glaucoma and progression or development of cataracts.

Where is the study run from?
King's College Hospital NHS Foundation Trust

When is the study starting and how long is it expected to run for?
June 2011 to December 2012

Who is funding the study?
Allergan (UK)

Who is the main contact?
Dr Sobha Sivaprasad

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
11/H0718/6

Study information

Scientific Title
An exploratory phase III prospective open-label clinical study on monthly Optical Coherence Tomography (OCT) monitoring of the effects of Ozurdex for macular oedema related to retinal vascular diseases (OCTOME Study)

Acronym
OCTOME study

Study objectives
Ozurdex was given every 6 months, if indicated, in the GENEVA trial on Ozurdex for macular oedema secondary to retinal vascular occlusions The study results indicated that the maximum effect of the drug was at 3-4 months based on visual acuity data. The trial was not designed to monitor the anatomical effect every month. This is essential to understand the morphological impact of the drug. Visual acuity does not always correlate with clinical severity of macular oedema so other visual functions such as contrast sensitivity and colour vision and retinal sensitivity will give us a better understanding of the effect of Ozurdex on macular oedema.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central London REC 1, 11/04/2011, ref: 11/H0718/6

Study design
Exploratory Phase III prospective study on 30 patients with macular oedema secondary to retinal vascular disorders treated with OCT guided OZURDEX and monitored for 36 weeks.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Macular oedema

Interventions
1. Ozurdex 700µg dose intravitreal implant will be given to all patients at baseline
2. Patients will then be followed up 4 weekly for 36 weeks
3. Re-treatment with the same drug is allowed at 16th, 20th or 24th week
4. Each patient will receive a maximum of 2 injections
5. Re-treatment is allowed from week 16 to 24 inclusive if the following criteria are met after an initial improvement (reduction) of macular thickness of at least 50 µm:
5.1. Average macular thickness increases by 100 µm or more from the last visit AND
5.2. At least a 5 letter drop in BCVA score from the previous visit
5.3. However, please note that a second injection should not be administered if the patient experienced raised IOP above 30mmHg at any point
6. The last follow up for patients included in the study will be at week 36
7. All patients will have an additional visit for a safety check 5-7 days after treatment(s)

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Mean change in OCT at 4 weekly time points

Key secondary outcome(s))
1. Mean change in macular thickness at week 24
2. Mean change in visual acuity at week 24
3. Proportion with gain of 15 ETDRS letters or more (improvement) from screening at week 24
4. Proportion with loss less than 15 ETDRS letters (stabilization) from screening at week 24
5. Proportion of patients with gain of 0, 5 and 10 letters from screening at week 24
6. Mean Change in other visual functions at week 24:
6.1. Change in contrast sensitivity
6.2. Change in colour vision
6.3. Change in reading vision
6.4. Change in microperimetry thresholds
6.5. Change in fixation on microperimetry
7. Efficacy parameters that will be assessed at week 36:
7.1. Mean change in visual acuity and macular thickness at week 36
7.2. Proportion with gain of 15 ETDRS letters or more (improvement) from screening at week 36

7.3. Proportion with loss less than 15 ETDRS letters (stabilization) from screening at week 36
7.5. Proportion of patients with recurrence of oedema (increase macular thickness by 100µm from baseline to 36 weeks at each 4 weekly time point from baseline

Completion date
08/12/2012

Eligibility

Key inclusion criteria
1. Aged 18 or above
2. Ability to provide informed consent
3. Diagnosis of macular oedema secondary to diabetic maculopathy, branch and central retinal vein occlusion or pseudophakic cystoid macular oedema or post-inflammatory macular oedema
4. Central macular thickness on OCT should be above 250µm
5. Best corrected visual acuity in the study eye between 37 and 68 letters

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Any other eye disease which could mask macular oedema
2. Known uncontrolled systemic disease or current immunosuppressive disease
3. Initiation of medical therapy for diabetes or a change from oral hypoglycaemic agents to insulin therapy within 4 months prior to the screening visit
4. Renal failure requiring haemodialysis or peritoneal dialysis within 6 months prior to screening visit
5. Any ocular condition in the study eye that in the opinion of the investigator would prevent a 15-letter improvement in visual acuity (e.g., severe macular ischemia, extensive macular laser scarring or atrophy)
6. Presence of an epiretinal membrane or vitreo-retinal interface changes in the study eye which, in the opinion of the investigator, is the primary cause of macular oedema, or is severe enough to prevent improvement in visual acuity despite reduction in macular oedema
7. Active or suspected ocular or periocular infection including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases
8. Advanced glaucoma which cannot be adequately controlled by medicinal products alone
9. History of IOP elevation in response to steroid treatment in either eye that resulted in any of

the following:
9.1. >10 mm Hg increase in IOP from baseline with an absolute IOP > 25 mm Hg
9.2. Required therapy with 3 or more anti-glaucoma medications
10. Pregnancy if child bearing age (confirmed by pregnancy test) and to avoid pregnancy during the 36 weeks of the study. Pregnancy test will not be done in post-menopausal women (defined as 12 months post LMP)
11. Breast feeding women will be excluded
12. Hypersensitivity to the active substance or to any of the excipients
13. Inability to provide informed consent

Date of first enrolment
08/06/2011

Date of final enrolment
08/12/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College Hospital NHS Foundation Trust
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College NHS Foundation Trust (UK)

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Industry

Funder Name
Allergan (UK) ref: MAF-ISS-OPH-RET-002CTA

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?
Results article	results	01/03/2014		Yes	No
HRA research summary			28/06/2023	No	No