ISRCTN87077451 https://doi.org/10.1186/ISRCTN87077451

Does Diamox have a significant effect on intraocular pressure after a Lucentis injection therapy in Glaucoma patients?

Submission date
16/02/2012

Recruitment status
No longer recruiting

Registration date
26/04/2012

Overall study status
Completed

Last Edited
08/09/2015

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
Age-related macular degeneration (AMD) is a leading cause of irreversible blindness among people who are 50 years of age or older in the developed world. The neovascular (wet) type of AMD is caused by the abnormal growth of blood vessels in the eye, which leak and damage the eye. The result is severe loss of vision and untreated this can lead to rapid irreversible blindness. The drug ranibizumab (Lucentis) is now the standard treatment for wet AMD. Treatment involves a course of injections into the eye. One of the potential side affects of the injections is raised eye pressure. In high-risk glaucoma patients this may lead to further loss of vision. In our study we aim to measure eye pressure trends in glaucoma patients undergoing Lucentis injections for wet AMD. The study will also evaluate the use of a tablet called acetazolamide (Diamox) to lower eye pressure spikes in these patients.

Who can participate?
Patients with neovascular (wet) AMD and glaucoma.

What does the study involve?
Participants will be randomly allocated to be treated with either Lucentis injections or both acetazolamide tablets and Lucentis injections.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Lucentis Eye Clinic, York Teaching Hospital (UK).

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

Who is funding the study?
York Teaching Hospital NHS Foundation Trust (UK).

Who is the main contact?
Mr Richard Gale
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2010-023037-35

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
YORA01567 Eudract 2010-023037-35

Study information

Scientific Title
Short term intraocular pressure trends in high risk patients following intravitreal Ranibizumab (Lucentis) injections for wet age related macular degeneration - is there a role for systemic Acetazolamide (Diamox) in those with glaucoma?

Acronym
LIEPS

Study objectives
The Lucentis Injection Eye Pressure Study (LIEPS):
Neovascular Age related macular degeneration (nAMD) in Glaucoma/Glaucoma suspect patients is characterised by the abnormal growth of blood vessels at the macula which is the central part of the retina concerned with high resolution vision. These new blood vessels leak and haemorrhage which leads to damage of the retinal layers. The result is severe loss of central vision and untreated this can lead to rapid irreversible central blindness.

Null hypothesis:
Prophylactic use of (intraocular pressure) IOP lowering Acetazolamide (Diamox) will not significantly reduce IOP rise following intravitreal injections of Ranibizumab (Lucentis) for neovascular (wet) age-related macular degeneration (AMD) in glaucoma patients

Hypothesis:
Prophylactic use of IOP lowering Acetazolamide (Diamox) will significantly reduce IOP rise following intravitreal injections of Ranibizumab (Lucentis) for neovascular (wet) AMD in glaucoma patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee North East - Northern & Yorkshire, 05/05/2011, ref: 10/H0903/57

Study design
Open-label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
This will be a two-arm study with patients randomised to receive:

Arm A: Lucentis injection
Arm B: Two 250 mg Acetazolamide tablets [followed within 60-90 minutes] by Lucentis injection

Arm A
1. There will be no need for placebo tablets in this trial. This arm of recruits will receive a Lucentis injection only.
2. This arm of recruits is the control group. They will only receive a Lucentis injection as per standard package of care. They will not receive any additional IMP tablets.
3. Dispensing - The research nurse will take a completed prescription form for each eligible

patient to York Hospital pharmacy. The pharmacy will then dispense according to their randomisation. If randomised to the control group, patients will not receive IMP tablets. These recruits will then be part of Arm A. If randomised to receive IMP tablets, recruits will join Arm B and the following will apply: Tablets will be open label. Trial products will be dispensed in packs each containing 2 tablets and labelled as per Annex 13 of Volume 4 of The Rules Governing Medicinal Products in the EU: Good Manufacturing Practices. Pharmacy will provide an example label required for MRHA application.

Arm B
1. Oral Acetazolamide (Diamox) is a systemic carbonic anhydrase inhibitor that has been in use for over 50 years to reduce intraocular pressure. It is currently already in use in York and other national hospital Lucentis injection clinics for glaucoma and ocular hypertension patients. York Teaching Hospital Pharmacy will provide Acetazolomide tablets for this trial. The prophylactic dose of 500mg is administered orally 60-90 minutes prior to injection. 2X 250mg tablets will be dispensed per patient and taken orally as directed. York Teaching Hospital Pharmacy will store the tablets at ambient temperature.
2. 2x 250 mg Acetazolamide tablets will be taken orally by the patient 60-90 minutes prior to Lucentis injection.
3. The research nurse will take a completed prescription form for each eligible patient to York Hospital pharmacy. The pharmacy will then dispense according to their randomisation. If randomised to the control group, patients will not receive IMP tablets. These recruits will then be part of Arm A. If randomised to receive IMP tablets, recruits will join Arm B and the following will apply: Tablets will be open label. Trial products will be dispensed in packs each containing 2 tablets and labelled as per Annex 13 of Volume 4 of The Rules Governing Medicinal Products in the EU: Good Manufacturing Practices. Pharmacy will provide an example label required for MRHA application.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Acetazolamide (Diamox), ranibizumab (Lucentis)

Primary outcome measure
Mean IOP (intraocular pressure) change from baseline (T-B) immediately after injection (T0), 5 minutes (T5), 10 minutes (T10) and 30 minutes (T30). A handheld tonometer will be used to measure the IOP.

Secondary outcome measures
No secondary outcome measures

Overall study start date
16/09/2011

Completion date
16/09/2012

Eligibility

Key inclusion criteria
1. Patients with neovascular (wet) AMD requiring Lucentis injections
2. Glaucoma
3. Glaucoma suspect
4. Written informed consent
5. Baseline pre-injection IOP of less than 30mmHg

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
24 patients are required for this 2 arm study to provide 80% power and 5% significance

Key exclusion criteria
1. Baseline pre-injection IOP of 30 mmHg or higher
2. Unable to give written informed consent
3. Known allergy to sulphur/sulphonamide containing drugs or acetazolamide
4. 18 years or younger
5. Marked kidney or liver disease/dysfunction
6. Supra-renal gland failure
7. Hyperchloremic acidosis
8. Hepatic cirrhosis
9. Pregnancy / [Pre]-menopausal
10. Concomitant use of other oral carbonic anhydrase inhibitors

Date of first enrolment
16/09/2011

Date of final enrolment
16/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

York Teaching Hospital NHS Foundation Trust
York
United Kingdom
YO31 8HE

Sponsor information

Organisation
York Teaching Hospital NHS Foundation Trust (UK)

Sponsor details
North and East Yorkshire Alliance
Research & Development Unit
Learning and Research Centre
York
England
United Kingdom
YO31 8HE

Sponsor type
Hospital/treatment centre

Website
http://www.york.nhs.uk/

ROR
https://ror.org/027e4g787

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
York Teaching Hospital NHS Charitable Foundation Trust (UK) - Elsie May Sykes Award

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2014		Yes	No
HRA research summary			28/06/2023	No	No