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Ranibizumab for DMO PRP trial (RDP trial)

Submission date	Recruitment status	[_] Prospectively registered
18/03/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/03/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/04/2023	Eye Diseases	

Plain English summary of protocol

Background and study aims
The most common cause of loss of vision in diabetes is macular oedema. Diabetes can cause a condition called retinopathy where high blood glucose levels cause damage to the tiny blood vessels lining the surface of the back of the retina. This can result in the growth of new, abnormal blood vessels which may leak blood or fluid into the eye. If this happens in the most sensitive region of the retina, the macula, it causes the area to swell (oedema). Over time, this can lead to scarring and loss of vision. Ranibizumab is a drug used to treat diabetic macular oedema. It is given as an injection into the eye. Whilst it can work well, a large number of injections may be needed over a number of years. Ranibizumab works by preventing the growth of abnormal blood vessels. It is thought that macular oedema is mainly caused by changes in the central blood circulation in the retina. However, it is possible that poor circulation in the peripheral areas of the retina (peripheral ischemia) can lead to an increase in vascular endothelial growth factor (VEGF) levels (a protein that stimulates the growth of blood vessels) which may result in the recurrence of macular oedema, at least in a subset of patients. It has only recently become possible to visualize the degree of peripheral ischaemia with an imaging technique called widefield fluorescein angiography (wFFA). It is therefore possible to target the area of ischaemia with a laser that might reduce VEGF levels and stabilize macular oedema, making the treatment more acceptable for patients, more cost effective and lead to better long term visual results. The aim of this study is to compare the treatment of macular oedema and peripheral ischaemia with a combination of ranibizumab and retinal laser treatment with ranibizumab alone.

Who can participate?
Adults with macular oedema caused by diabetic retinopathy.

What does the study involve?
Participants are randomly allocated into one pf two groups. Those in group 1 are treated with ranibizumab and retinal laser treatment. Those in group 2 are treated only with the ranibizumab. The treatments are assessed in terms of how long it is before each participant needs a repeat ranibizumab injection, number of injections needed in a year and the participants visual acuity (acuteness/clearness of vision) after a year.

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

Where is the study run from?
Newcastle upon Tyne Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2014 to December 2015

Who is funding the study?
Novartis Pharmaceuticals UK Limited

Who is the main contact?
Mr Sean Scott

Contact information

Type(s)
Scientific

Contact name
Mr Sean Scott

Contact details
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Additional identifiers

Protocol serial number
15819

Study information

Scientific Title
Randomized trial of widefield guided PRP for diabetic macular oedema (DMO) treated with ranibizumab

Acronym
RDP

Study objectives
Ranibizumab is licensed for the treatment of diabetic macular oedema. It is given as an injection into the eye. Whilst it can work well a large number of injections may be needed over a number of years. Ranibizumab works by blocking vascular endothelial growth factor (VEGF). The main pathology causing the oedema maybe due to changes in the central retinal circulation but it is possible that peripheral ischaemia, which is a poor circulation in the peripheral areas of the retina, leads to an increase in VEGF levels and so drives the recurrence of macular oedema, at least in a subset of patients. It has only recently become possible to visualize the degree of

peripheral ischaemia with widefield fluorescein angiography (wFFA). It is therefore possible to target the area of ischaemia with peripheral laser that might reduce VEGF levels and so help lead to stabilization of the macular oedema and so make the treatment more acceptable for patients, more cost effective and lead to better long term visual results. In this study patients with macular oedema and peripheral retinal ischaemia will be treated with ranibizumab but randomized to additional retinal laser. The main outcomes will be the length of time a patient does not require an injection, after the initial loading phase. Number of injections in a year and the difference in visual acuity at the end of one year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13-NE-0197

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Diabetes, Ophthalmology; Subtopic: Both, Eye (all Subtopics); Disease: Retinopathy, Ophthalmology

Interventions
Patients with OCT confirmed DMO and wFFA confirmed peripheral retinal ischaemia will be randomised to PRP + Ranibizumab or Ranibizumab monotherapy as per pre-defined criteria. Study Entry : Single Randomisation only

Intervention Type
Procedure/Surgery

Primary outcome(s)
Number of repeat Ranibizumab injections required after the first 6 months up until one year post treatment

Key secondary outcome(s)
1. Length of treatment free interval
2. Difference in visual acuity at one year
3. Difference in time

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Visual acuity 20/30 to 20/300
2. Macular oedema secondary to diabetic retinopathy. (OCT Thickness of >300 micrometres central subfield, on spectral domain OCT (Spectralis OCT Heidelberg engineering)
3. EDTRS grade 53 – 57 up to non high-risk proliferative diabetic retinopathy
4. Peripheral ischaemia seen on wFFA
5. Patient able to give consent and take part in all study procedures
6. In the opinion of the investigator the patient should benefit from treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Visual acuity worse than 20/300
2. Rubeosis
3. Proliferative retinopathy with high risk characteristics
4. Unable to give consent or take part in all study procedures
5. Other conditions that might interfere with the assessment of the eye such as cataract or prevent the macular oedema from settling such as vitreomacular traction, epiretinal membrane, to a degree that would in the opinion of the investigator affect response to treatment; conditions that would prevent the visual acuity improving such as foveal atrophy, uveitis
6. Previous macular laser within 3 months in the study eye
7. Previous peripheral (PRP) laser in the study eye
8. Previous injection therapy within last 4 months (anti VEGF) 6 months (steroid) in the study eye
9. Pregnant
10. Uncontrolled systemic illness that in the opinion of the investigator would preclude involvement
11. Cataract or other intraocular surgery within 3 months
12. Previous vitrectomy

Date of first enrolment
01/04/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newcastle upon Tyne Hospitals NHS Trust
Queen Victoria Road
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharmaceuticals UK Limited

Alternative Name(s)
Novartis UK, NOVARTIS UK LIMITED

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		06/02/2019	25/04/2023	Yes	No