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Combination therapy of Visudyne, Minocycline, Dexamethasone and Ranibizumab (VIMDER) for the treatment of subfoveal choroidal neovascularisation (CNV)

Submission date
20/11/2007

Registration date
30/05/2008

Last Edited
13/11/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Eye Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
06NB37

Study information

Scientific Title

A pilot study to examine the safety and efficacy of intravitreal ranubizumab/dexamethasone administration and oral minocycline in addition to Visudyne (verteporfin) photodynamic therapy for subfoveal choroidal neovascularization secondary to age-related macular degeneration: an open-label trial

Acronym
ViMDeR (Visudyne, Minocycline, Dexamethasone and Ranubizumab)

Study objectives
To assess the safety and effectiveness of the combined therapy of intravitreal ranubizumab /dexamethasone, oral minocycline and verteporfin photodynamic therapy for subfoveal choroidal neovascularisation (CNV) secondary to age-related macular degeneration (AMD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the King's College Hospital Research Ethics Committee in June 2007.

Study design
Non-randomised, non-controlled pilot trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Age-related macular degeneration

Interventions
Patients will receive a reduced light dose (25 J/cm^2) verteporfin photodynamic therapy, and an intravitreal injection of 0.3 mg ranibizumab and 200 µg dexamethasone at their first visit. Minocycline 100 mg taken orally (p.o) will be taken daily for three months. Duration of follow up is one year.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Verteporfin, anibizumab, dexamethasone, minocycline

Primary outcome(s)
Evaluate the changes in visual acuity from baseline at 12 months in patients treated with intravitreal ranibizumab in combination with verteporfin photodynamic therapy.

Key secondary outcome(s))
1. Mean change from baseline in best corrected visual acuity (BCVA) at month six
2. Proportion of patients who gain greater than or equal to 5, 10, 15 letters of BCVA from baseline at months 6 and 12
3. Proportion of patients who lose less than 15 letters of BCVA from baseline at months 6 and 12
4. Mean change from baseline in total size of lesion and total size of CNV at 3, 6, and 12 months
5. Change in area of leakage at 3, 6 and 12 months
6. Total number of treatments of Lucentis
7. Mean time to first re-treatment following the initial combination therapy
8. Mean change in retinal lesion thickness by optical coherence tomography (OCT) at centre of fovea at 3, 6, and 12 months

Completion date
01/06/2008

Eligibility

Key inclusion criteria
1. The patient must be willing to give written informed consent
2. The patient must be able to undertake the necessary tests and treatment and be willing to be followed up
3. Age 50 years or older
4. Clinical diagnosis of AMD
5. Subfoveal CNV confirmed by fluorescein angiography
6. Logarithmic minimal angle of resolution (LogMAR) best corrected visual acuity of 24 - 73 letters on early treatment diabetic retinopathy study (ETDRS) chart

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Inability to understand or sign consent form
2. The patient has a current medical condition or history of a medical condition that would be likely to preclude scheduled study visits such as unstable angina, dialysis, and active cancer
3. Patient has a current ophthalmic condition or history of an ophthalmic condition that might compromise the assessment of the treatment such as diabetic retinopathy, uveitis, amblyopia, ischaemic optic neuropathy
4. Signs of a myopic retina or refraction of greater than -8 dioptres in their current or any previous glasses prescription
5. Signs of other retinal conditions that may have caused the CNV such as angioid streaks,

choroidal rupture, and old chorio-retinitis
6. Open angle glaucoma
7. At increased risk of developing glaucoma such as having pigment dispersion syndrome or pseudoexfoliation
8. Unable to have a good quality fluorescein angiogram taken, e.g., due to head tremor or media opacity
9. Known hypersensitivity to fluorescein or any of the study medications
10. Previous treatment for a retinal detachment
11. Judged by the examining clinician to be at increased risk of retinal detachment due to weaknesses in the peripheral retina
12. Previous photodynamic therapy or other therapy for a CNV including argon laser treatment
13. Patient is currently participating or has participated in a clinical trial that utilised an investigational drug or treatment within 30 days prior to enrolment to this study
14. On anticoagulation therapy such as warfarin, with the exception of aspirin and other anti-platelet therapy
15. Exclusion of women of childbearing potential
16. Exclusion of pregnant or lactating women

Date of first enrolment
01/06/2007

Date of final enrolment
01/06/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College Hospital
London
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SE5 9RS

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
University/education

Funder Name
King's Research Fund (UK)

Funder Name
Novartis Pharmaceuticals UK Limited (UK)

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 of pilot study	01/12/2011		Yes	No