

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

Submission date 20/11/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/05/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/11/2017	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non 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

Age-related macular degeneration

Interventions

Patients will receive a reduced light dose (25 J/cm²) 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 measure

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

Secondary outcome measures

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

Overall study start date

01/06/2007

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

Age group

Adult

Sex

Both

Target number of participants

20

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

England

United Kingdom

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

Sponsor information

Organisation

King's College Hospital NHS Foundation Trust (UK)

Sponsor details

c/o Ernest Choy
Denmark Hill
London
England
United Kingdom
SE5 9RS

Sponsor type

Hospital/treatment centre

Website

<http://www.kch.nhs.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

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 of pilot study	01/12/2011		Yes	No