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

Submission date 20/11/2007	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 30/05/2008	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 13/11/2017	<b>Condition category</b> Eye Diseases	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

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/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 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 antiplatelet 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