# Age related macular degeneration pharmacogenetics study

Submission date	Recruitment status	Prospectively registered
28/05/2010	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/05/2010	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
29/08/2013	Eye Diseases	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Mr Martin McKibbin

#### Contact details

Leeds Teaching Hospitals NHS Trust Department of Opthalmology St James's University Hospital Leeds United Kingdom LS9 7TF

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 7380

# Study information

#### Scientific Title

Genotype and response to treatment for age related macular degeneration (ARMD): a multicentre, non-randomised, interventional, cohort study

#### **Study objectives**

There has been a major advance in our understanding of the genetic and environmental causes of age related macular degeneration (ARMD). Research has implicated smoking and genetic variants in the complement factor pathway and the HTRA1, vascular endothelial growth factor (VEGF) and a number of other genes of lesser effect, in susceptibility to ARMD.

There has also been a parallel advance in the ability to treat this common, blinding disorder using anti-VEGF based treatments, and in particular the VEGF antibody ranibizumab (Lucentis®). This proposal aims to test the hypothesis that response to intravitreal ranibizumab injections in ARMD is, at least in part, modulated by genotype. If genotype does predict response, alternative treatments could be used in those found to benefit least, increasing success rates, saving sight and reducing the need for unnecessary intravitreal injections.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Leeds East Research Ethics Committee approved in February 2009 (ref: 08/H1306/123)

#### Study design

Multicentre non-randomised interventional prevention and treatment trial

## Primary study design

Interventional

# Secondary study design

Non randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

#### Participant information sheet

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

Topic: Eye; Subtopic: Eye (all Subtopics); Disease: Ophthalmology

#### **Interventions**

This study aims to determine whether genotypes for single nucleotide polymorphisms (SNPs) in the complement factor H, HTRA1 and VEGF genes can predict response to treatment with ranibizumab in patients with ARMD.

The visual acuity change from baseline, in ETDRS letters, will be collected from patients who have completed 6 months of treatment for neovascular AMD with intra-vitreal ranibizumab therapy, given in accordance with the EMEA marketing authorisation. DNA will be collected from

study participants and genotyped for SNPs in the following genes: HTRA1, VEGF and CFH. The data will be analysed to determine if there is evidence of an association between genotype and treatment outcome.

Follow-up length: 6 months Study entry: registration only

#### Intervention Type

Other

#### **Phase**

Phase IV

#### Primary outcome measure

Association of visual acuity letter score change after 6 months of treatment with intra-vitreal ranibizumab and CFH, HTRA1 and VEGF genotype.

#### Secondary outcome measures

- 1. Association of visual acuity letter score change after 6 months of treatment with intra-vitreal ranibizumab and baseline visual acuity
- 2. Smoking history
- 3. Sex
- 4. Lesion type
- 5. Number of injections
- 6. Prior treatment status

# Overall study start date

31/03/2009

## Completion date

01/03/2011

# **Eligibility**

#### Key inclusion criteria

- 1. Aged over 65 years, either sex
- 2. Affected with ARM
- 3. Currently under treatment with ranibizumab (Lucentis)
- 4. Patients with lesions of greatest linear diameter less than 5400 microns

# Participant type(s)

Patient

#### Age group

Senior

#### Sex

Both

# Target number of participants

Planned sample size: 350; UK sample size: 350

#### Key exclusion criteria

- 1. Patients with poor general health
- 2. Patients with other eye pathology likely to affect response to treatment
- 3. Patients with lesions of greatest linear diameter greater than 5400 microns
- 4. Patients currently being treated with other anti-VEGF agents (systemic or ocular)

#### Date of first enrolment

31/03/2009

#### Date of final enrolment

01/03/2011

# Locations

#### Countries of recruitment

England

**United Kingdom** 

## Study participating centre Leeds Teaching Hospitals NHS Trust

Leeds United Kingdom LS9 7TF

# Sponsor information

#### Organisation

Leeds Teaching Hospitals NHS Trust (UK)

#### Sponsor details

Trust Headquarters
St James University Hospital
Beckett Street
Leeds
England
United Kingdom
LS9 7TF

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.leedsteachinghospitals.com/

#### **ROR**

https://ror.org/00v4dac24

# Funder(s)

#### Funder type

Research organisation

#### **Funder Name**

National Eye Research Centre (NERC) (UK)

#### Alternative Name(s)

National Eye Research Centre, SightResearchUK, SRUK, NERC

#### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Universities (academic only)

#### Location

**United Kingdom** 

#### **Funder Name**

Novartis Pharmaceuticals UK Ltd (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 articleresults01/02/2012YesNoHRA research summary28/06/2023NoNo