ISRCTN44202629 https://doi.org/10.1186/ISRCTN44202629

Age related macular degeneration pharmacogenetics study

Submission date 28/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/05/2010	**Overall study status** Completed	
Last Edited 29/08/2013	**Condition category** 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 particpants and genotyped for SNPs inthe 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 article	results	01/02/2012		Yes	No
HRA research summary			28/06/2023	No	No