A Study of Disease Progression in Genetically Defined Subjects With Geographic Atrophy Secondary to Age-Related Macular Degeneration

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To evaluate the natural progression of anatomical and functional visual parameters in genetically defined subjects with Geographic Atrophy (GA) due to Age-related Macular Degeneration (AMD).

Ethical review	Approved WMO
Status	Completed
Health condition type	Vision disorders
Study type	Observational invasive

Summary

ID

NL-OMON52960

Source
ToetsingOnline

Brief title
GTSCOPE study

Condition

- Vision disorders

Synonym
Age-Related Macular Degeneration, Geographic Atrophy

Research involving
Human

Sponsors and support

Primary sponsor: Gyroscope Therapeutics Limited

Source(s) of monetary or material Support: Gyroscope Therapeutics Limited

Intervention

Keyword: Dry Age-Related Macular Degeneration (Dry AMD), Geographic Atrophy (GA)

Outcome measures

Primary outcome

The following endpoints will be assessed:

- GA area size as assessed by Fundus Autofluorescence (FAF)

- Best Corrected Visual Acuity (BCVA) Score as assessed by Early Treatment Diabetic Retinopathy Study (ETDRS) Chart in standard and low luminance conditions

- Rate of GA progression based on anatomical findings on colour fundus photography and Spectral Domain Optical Coherence Tomography (SD-OCT)

- Monocular and Binocular Reading Speed as assessed by Minnesota Low-Vision Reading Test (MNRead) Chart

- Quality of life (QoL) score as measured by National Eye Institute Visual Functioning Questionnaire 25-item Version (NEI VFQ-25)

- Retinal sensitivity as assessed by microperimetry

- Percentage of Participants with Medical Events of Interest (MEIs)

Secondary outcome

N/A

Study description

Background summary

Dry AMD is a disease of the retina that results in loss of vision in the macula (center of the eye). When Dry AMD progresses, this can lead to a condition called Geographic Atrophy (GA) causing further loss of vision due to degeneration of the cells in the retina. Eventually, this may lead to blurred or loss of vision that affects one or both eyes.

There is currently no treatment available for Dry AMD.

A family history of Dry AMD increases the risk of developing the disease, which suggests there is a genetic link. It has also been shown that over-activation of a part of the immune system called the complement system further contributes to the disease.

A recent study has shown that subjects with a known family history risk who have an over-active complement system are at an even higher risk of developing severe Dry AMD disease than subjects that do not have these two risk factors.

Study objective

To evaluate the natural progression of anatomical and functional visual parameters in genetically defined subjects with Geographic Atrophy (GA) due to Age-related Macular Degeneration (AMD).

Study design

This is an observational study to evaluate the natural progression of anatomical and functional visual parameters in genetically defined subjects with GA due to AMD. For each subject, the study will consist of 7 visits over approximately 96 weeks. Subjects may be withdrawn if they become eligible for an interventional study. All participating subjects will undergo functional visual and retinal imaging/anatomical assessments over the study period.

Study burden and risks

Subjects will be screened for eligiblity over a 4 to 6 week period and then observed over a 96 week period. Subjects may be withdrawn if they become eligible for an interventional study.

Subjects being considered for inclusion will be required to sign a genotyping consent form, agreeing to provide a sample for genetic testing/or permit the analysis of an existing sample. Samples will be collected and shipped to a

Central Laboratory for genotyping. A remote sample kit may be sent by the investigator site to the subject*s home address, with instuctions on how to collect a saliva sample and ship to the Central Laboratory. If more practical, the subject may be invited to the investigator site clinic for sample collection. In some cases blood or saliva samples that have been taken prior to study entry and stored within the investigator site*s biobank may be used for genotyping.

At the screening/baseline visit, subjects will be required to sign the full study informed consent form for participation in the study. Following signature of the full study informed consent form, the following assessments will be completed at the subjects* study site:
- Baseline demographics, medical/surgical history, current/ongoing medications
- Blood samples for CFI and biomarker analyses
- Standard ophthalmic examination for both eyes
- ETDRS BCVA. Measured for both eyes in standard and in low luminance conditions.
- FAF
- 3-field Colour Fundus Photography (CFP)
- SD-OCT
- Retinal sensitivity via mesopic Microperimetry
- Monocular and binocular reading speed using MnRead tool
- QoL using NEI VFQ-25

Subsequent follow-up visits will be scheduled at 12, 24, 48, 72, and 96 weeks. Both eyes will be assessed and analysed for disease progression.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inclusion Criteria:, 1. Aged >=18 years, 2. Able and willing to give consent to study participation, 3. Presence of unilateral or bilateral GA due to AMD, 4. The GA lesion in at least one eye must reside completely within the FAF image, 5. For Group 1, subjects will be required to have a serum CFI level below the lower limit of the assay together with a
rare genetic variant of the CFI gene OR for Group 2, subjects will have a genetic variant of a complement factor
gene and do not qualify for Group 1, 6. Able to attend all study visits and complete the study procedures, 7. BCVA of 40 letters or better using ETDRS charts in the eye that meets inclusion criterion 3

Exclusion criteria

Exclusion Criteria:, 1. Evidence or history of neovascular AMD or diabetic retinopathy; previous intravitreal drug delivery
[either eye] received within 4 weeks or 5 half-lives whichever is longer, before screening/baseline visit, 2. Any other significant ocular or non-ocular disease/disorder which, in the opinion of the investigator,
may influence the results of the study, or the subject*s ability to participate in the study, 3. Participation in another research study involving an investigational product within the previous 4 weeks
or 5 half-lives whichever is longer, from the screening/baseline visit OR received a gene/cell therapy at
any time previously

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-11-2019
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-08-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-11-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-01-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL68811.091.19