ORACLE: A long-term follow-up study to evaluate the safety and durability of GT005 in participants with geographic atrophy, secondary to age-related macular degeneration treated in a Gyroscope-sponsored antecedent study.

Published: 21-12-2022
Last updated: 07-04-2024

The overall objectives of the study are to evaluate the long-term safety and durability of GT005 in participants with GA secondary to AMD who have been treated in an antecedent study.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON56154

Source
ToetsingOnline

Brief title
GT-ORACLE

Condition

- Vision disorders

Synonym
Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Research involving

Human

Sponsors and support

Primary sponsor: Gyroscope Therapeutics Ltd.
Source(s) of monetary or material Support: Industry

Intervention

Keyword: Age-related Macular Degeneration (AMD), Gene Therapy, Geographic Atrophy (GA)

Outcome measures

Primary outcome

To evaluate the long-term safety of GT005

Secondary outcome

To evaluate the long-term durability of GT005 on GA progression.

To evaluate the long-term durability of GT005 on functional measures

Study description

Background summary

GT005, a recombinant adeno-associated viral serotype 2 (AAV2) vector encoding for human complement factor I, is currently being developed as a potential gene therapy for GA secondary to AMD.
Current regulatory guidelines [EMA 2009; EMA 2018; FDA 2020] recommend that participants enrolled in gene therapy clinical trials with viral vectors that are non-replicating, non-integrating, and have no known potential for latency and re-activation should be followed for approximately 5 years post-treatment.
The aim of this study (GT-ORACLE) is to evaluate the long-term safety and durability of GT005 for up to 5 years post-treatment.
All participants treated with GT005 in the GT005-02 (EXPLORE, NCT04437368) and GT005-03 (HORIZON, NCT04566445) study will be invited to enrol in this long-term, follow-up study.

Study objective

The overall objectives of the study are to evaluate the long-term safety and durability of GT005 in participants with GA secondary to AMD who have been treated in an antecedent study.

Study design

This is a prospective, multi-centre, long-term, follow-up study for participants who received GT005 in an antecedent clinical study (GT005-02 or GT005-03). No further investigational product will be administered within this study, and participants will be invited to enter ORACLE upon their completion of the antecedent interventional study. This study will consist of five study visits and two phone calls for up to a 5-year period post-GT005 administration. Following consent, the participants will be asked to attend the following visits (dates are determined according to the date of GT005 administration in the antecedent study): Visit 1 (Week 96 post-GT005 administration, should coincide with the final visit of antecedent study); Visit 2 (Week 126 post-GT005 administration); Visit 3 (Week 156 [3 years] post-GT005 administration); Phone call 1 (Week 182 [3,5 years] post-GT005 administration); Visit 4 (Week 208 [4 years] post-GT005 administration); Phone call 2 (Week 234 [4,5 years] post-GT005 administration); and Visit 5 (Week 260 [5 years] post-GT005 administration).
At each visit, an attempt should be made to perform all ophthalmic procedures in both eyes. Each eye should be tested separately. If the participant is unable to complete a procedure for any reason, this should be documented in the source notes.
Participants who develop cataracts during the study may undergo cataract surgery if deemed clinically necessary. If cataract surgery is performed, it should be carried out at least 4 weeks before the next study visit.
In the case of unscheduled ocular surgery (e.g., cataract), a vitreous and/or aqueous sample may be taken during surgery. Each participant must provide a separate study consent for vitreous or aqueous samples to be taken, if the occasion arises.
The end of the study will be defined as the last visit by the last participant.
All participants will be followed up, post-study, as per normal standard of care for their disease and at the discretion of the Investigator.

Intervention

Not applicable

Study burden and risks

The risk/benefit assessment for this long-term follow-up study is considered favourable, as no significant risks have been identified with study participation. Moreover, future patients are anticipated to benefit from the evaluation of the long-term durability and safety evaluation of GT005 treatment

in participants with GA secondary to AMD.

Contacts

Public
Gyroscope Therapeutics Ltd.

Rolling Stock Yard York Way 188
London N7 9AS
GB
Scientific
Gyroscope Therapeutics Ltd.

Rolling Stock Yard York Way 188
London N7 9AS
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Able and willing to give written informed consent
2. Received GT005 in an antecedent study, GT005-02 (EXPLORE, NCT04437368 and GT005-03 (HORIZON, NCT04566445)
3. Willing to attend study visits and complete the study procedures.

Exclusion criteria

Not Applicable. If the participant is not able to attend Week 96 visit (End of Study visit for antecedent study) due to personal or medical reasons, the Sponsor should be consulted, and participant asked to attend the Study Centre at their next available opportunity to complete the Visit 1 for the ORACLE study.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO Date:	21-12-2022
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	31-05-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO	

Date:	26-06-2023
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2020-003987-22-NL
CCMO	NL83210.000.22
Other	www.clinicaltrialsregister.eu / clinicaltrials.gov