

A study to compare JNJ-81201887 to a sham procedure for the treatment of geographic atrophy secondary to age-related macular degeneration

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| Submission date 04/03/2023 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 20/09/2023 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 29/05/2025 | Condition category Eye Diseases | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Age-related macular degeneration (AMD) is an eye disease that can lead to vision loss. It happens when aging causes damage to part of the eye that controls sharp, straight-ahead vision. Geographic atrophy (GA) is an advanced form of AMD that leads to progressive and permanent loss of vision. JNJ-81201887 is a gene therapy that increases the ability of the retina cells to make CD59 (a protein that protects the retina from damage caused by an essential part of the body's natural immune response called the complement system), which may help prevent further damage. In this study, researchers want to see if JNJ-81201887 is effective in reducing the growth of GA lesions in the treated eye.

Who can participate?

Male and female participants 60 years or older

What does the study involve?

After screening, participants will be randomly assigned to one of the three groups and will receive treatment as an injection in the study eye on Day 4 as shown below:

1. Group A: Single low dose JNJ-81201887.
2. Group B: Single high dose of JNJ-81201887
3. Group C: Single sham procedure (a similar procedure that involves a syringe with no needle) will be performed.

In addition to JNJ-81201887, participants will receive oral prednisone for 20 days from Day 1 and a single long acting periocular triamcinolone (corticosteroid injection) around the eye on Day 4 in the eye for prevention of eye inflammation in Group A and B. Participants in Group C will receive a placebo that is matched to oral prednisone for 20 days from Day 1 and a sham corticosteroid injection around the eye similar to Group A and B on Day 4.

Participants will enter a long-term extension study after completion of the treatment to monitor for safety.

During the study, tests will be performed such as blood and eye tests (use of various tools to take images of the inside of the eye). Blood samples, eye fluid, and tears will be taken at multiple timepoints to understand how the body responds to treatment. All systemic and eye-related side effects will be recorded until the study ends (up to 1 year and 7 months for all participants).

What are the possible benefits and risks of participating?

There is no established benefit to participants of this study. Based on scientific theory, receiving JNJ-81201887 may improve AMD. However, this cannot be guaranteed because JNJ-81201887 is still under investigation as a treatment and it is not known whether JNJ-81201887 will work. If participants are put into the placebo or sham comparator group, they will not receive JNJ-81201887 and will only receive a placebo or sham procedure during this study. Participants may experience some benefit from participation in the study that is not due to receiving study drug, but due to regular visits and assessments monitoring overall health. Participation may help other people with AMD in the future.

Participants may have side effects from the drugs or procedures used in this study that may be mild to severe and even life-threatening, and these can vary from person to person. The most likely, known risks associated with the study intervention or concomitant medications are intraocular inflammation, hypertension, hyperglycemia, immune suppression and subsequent infection risk, mood changes, weight gain, osteoporosis, corneal abrasion, retinal detachment and cataract formation after getting the study drug or placebo. There are other, less frequent risks. The participant information sheet and informed consent form, which will be signed by every participant agreeing to participate in the study, includes a detailed section outlining the known risks of participating in the study. Not all possible side effects and risks related to JNJ-81201887 are known at this moment. During the study, the sponsor may learn new information about JNJ-81201887. The study doctor will tell participants as soon as possible about any new information that might make them change their minds about being in the study, such as new risks. To minimize the risk associated with taking part in the study, participants are frequently reviewed for any side effects and other medical events. Participants are educated to report any such events to the study doctor who will provide appropriate medical care. Any serious side effects that are reported to the sponsor are thoroughly reviewed by a specialist drug safety team. There are no costs to participants to be in the study. The sponsor will pay for the study drug and tests that are part of the study. The participant will receive reasonable reimbursement for study-related costs (e.g., travel/parking costs).

Where is the study run from?
Janssen (Netherlands)

When is the study starting and how long is it expected to run for?
March 2023 to January 2026

Who is funding the study?
Janssen Research and Development (USA)

Who is the main contact?
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Contact information

Type(s)

Scientific

Contact name

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Type(s)

Principal Investigator

Contact name

Prof Paulo Stanga

Contact details

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Additional identifiers

EudraCT/CTIS number

2022-500746-16

IRAS number

1006234

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

81201887MDG2001, IRAS 1006234, CPMS 53494

Study information

Scientific Title

A phase IIb, randomized, double-masked, multicenter, dose-ranging, sham-controlled clinical trial to evaluate intravitreal JNJ-81201887 (AAVCAGsCD59) compared to sham procedure for the treatment of geographic atrophy secondary to age-related macular degeneration

Acronym

PARASOL

Study objectives

Primary objective:

To assess the change in growth of geographic atrophy (GA) lesions in the eyes treated with JNJ-81201887 compared to sham control.

Secondary objectives:

1. To assess effect of JNJ-81201887 on low luminance visual acuity (LLVA).
2. To assess effect of JNJ-81201887 on visual function and retinal function.
3. To assess effect of JNJ-81201887 on best corrected visual acuity (BCVA).
4. To assess effect of JNJ-81201887 on functional reading independence and patient reported outcomes (PROs)

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 07/09/2023, London – West London & GTAC Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8098, (0)207 104 8007, (0)207104 8256; westlondon.rec@hra.nhs.uk), ref: 23/LO/0166

Study design

Phase IIb randomized double-masked parallel-group multicenter dose-ranging sham-controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Pharmaceutical testing facility

Study type(s)

Treatment, Safety, Efficacy

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Geographic atrophy, secondary to age-related macular degeneration

Interventions

Current interventions as of 29/05/2025:

After the screening, participants will be randomly assigned to one of the three groups and will receive treatment as an injection in the study eye on Day 4 as shown below:

1. Group A: Single low dose JNJ-81201887.
2. Group B: Single high dose of JNJ-81201887.
3. Group C: Single sham procedure (a similar procedure that involves a syringe with no needle) will be performed.

In addition to JNJ-81201887, participants will receive oral prednisone for 20 days from Day 1 and a single corticosteroid injection around the eye on Day 4 in the eye for prevention of eye inflammation in Group A and B. Participants in Group C will receive placebo-matched oral prednisone for 20 days and a sham corticosteroid injection around the eye similar to Group A and B from Day 1. Participants will enter a long-term extension study after completion of the treatment to monitor for safety. During the study, tests will be performed such as blood and eye tests (use of various tools to take images of the inside of the eye). Blood samples, eye fluid, and tears will be taken at multiple timepoints to understand how the body responds to treatment. All systemic and eye-related side effects will be recorded until the study ends (up to 1 year and 7 months).

Participants will be randomised centrally via an online tool (IWRS). Investigational sites will not be provided with randomisation codes.

Previous interventions:

After the screening, participants will be randomly assigned to one of the three groups and will receive treatment as an injection in the study eye on Day 4 as shown below:

1. Group A: Single low dose JNJ-81201887.
2. Group B: Single high dose of JNJ-81201887.
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Participants will be randomised centrally via an online tool (IWRS). Investigational sites will not be provided with randomisation codes.

Intervention Type

Biological/Vaccine

Pharmaceutical study type(s)

Pharmacodynamic, Genetic testing, biodistribution/shedding and immunogenicity

Phase

Phase II

Drug/device/biological/vaccine name(s)

JNJ-81201887 (AAVCAGsCD59)

Primary outcome measure

Current primary outcome measure as of 27/08/2024:

Change from baseline in square root of geographic atrophy (GA) lesion area in the study eye at Month 18

Previous primary outcome measure:

Change from baseline in square root of geographic atrophy (GA) lesion area in the study eye up to month 18

Secondary outcome measures

Current secondary outcome measures as of 27/08/2024:

1. Change From Baseline in Low Luminance Visual Acuity (LLVA) at Month 18
 2. Change From Baseline in Reading Speed at Month 18
 3. Change From Baseline in Retinal Sensitivity by Mesopic Microperimetry (MAIA) at Month 18
 4. Change From Baseline in Best Corrected Visual Acuity (BCVA) at Month 18
 5. Change From Baseline in Functional Reading Independence (FRI) Index at Month 18
 6. Change From Baseline in National Eye Institute Visual Functioning Questionnaire-25 (NEI-VFQ-25) Composite Score at Month 18
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Previous secondary outcome measures:

1. Change From Baseline in Low Luminance Visual Acuity (LLVA) up to Month 18
2. Change From Baseline in Reading Speed up to Month 18
3. Change From Baseline in Retinal Sensitivity by Mesopic Microperimetry (MAIA) up to Month 18
4. Change From Baseline in Best Corrected Visual Acuity (BCVA) up to Month 18
5. Change From Baseline in Functional Reading Independence (FRI) Index up to Month 18
6. Change From Baseline in National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25) Composite Score up to Month 18

Overall study start date

02/03/2023

Completion date

02/01/2026

Eligibility

Key inclusion criteria

Current inclusion criteria as of 27/08/2024:

1. Have non-subfoveal (defined as not involving the center point of the fovea) geographic atrophy (GA) secondary to age-related macular degeneration (AMD) with an area that can be measured and measures 2.5 millimeter square (mm^2) to 17.5 mm^2 (1- and 7- disc areas respectively), determined by the central reading center (CRC) from screening images of fundus autofluorescence (FAF) and spectral domain optical coherence tomography (SD-OCT).
2. If GA is multifocal, at least one focal lesion must be greater than or equal to (\geq) 1.25 mm^2 (0.5- disc area), as assessed by the CRC
3. GA can be photographed in its entirety by FAF, using a 30- degree image centered on the fovea, as assessed by the CRC.
4. Fellow eye must be present with a best corrected distance visual acuity (BCVA) of counting fingers or better.
5. Man or woman (according to their reproductive organs and functions assigned by chromosomal complement)

Previous inclusion criteria:

1. 60 years of age or older
2. Have non-subfoveal (defined as not involving the center point of the fovea) GA secondary to AMD with an area measuring 2.5 mm^2 to 17.5 mm^2 (1 and 7 disc areas respectively), determined by the CRC from screening images of FAF and SD-OCT.
3. A woman of childbearing potential must have a negative highly sensitive serum (β -human chorionic gonadotropin) test for the sample collected at Screening and a negative urine pregnancy test on Day 4 before receiving the study intervention.
4. Must sign an ICF (or their legally-acceptable representative must sign) indicating that the participant understands the purpose of, and procedures required for, the study and is willing to participate in and able to complete all required assessments during the study.

Participant type(s)

Patient

Age group

Mixed

Lower age limit

60 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

Current exclusion criteria as of 27/08/2024:

1. History of transpupillary thermotherapy, photodynamic therapy or external-beam radiation therapy in the region of study eye
2. Any prior thermal laser in the macular region, regardless of indication
3. History of retinal detachment (with or without repair)
4. Active, infectious conjunctivitis, keratitis, scleritis, or endophthalmitis
5. Any sign of diabetic retinopathy or central serous chorioretinopathy

Previous exclusion criteria:

1. History of or presence of retinal disease other than GA: diabetic retinopathy, central serous chorioretinopathy, inherited retinal degeneration, toxic maculopathies (ie, hydroxychloroquine maculopathy), arterial and venous occlusive disease, macular hole that is present or has been previously repaired, or choroidal melanoma.
2. Presence of macular fibrosis or retinal epithelial tear, clinically relevant myopic degeneration, or vitreous hemorrhage
 - a. Benign conditions of the vitreous (ie, posterior vitreous detachment) or peripheral retina (ie, paving stone degeneration, lattice degeneration, etc.) are permitted.
3. History of transpupillary thermotherapy, photodynamic therapy or external-beam radiation therapy in the region of study eye.
4. Any prior thermal laser in the macular region, regardless of indication.

Date of first enrolment

06/03/2023

Date of final enrolment

13/09/2024

Locations

Countries of recruitment

Argentina

Australia

Belgium

Brazil

Canada

Denmark

England

Germany

Hungary

Italy

Mexico

Netherlands

Poland

Portugal

Spain

Sweden

Switzerland

Türkiye

United Kingdom

Study participating centre

The Retina Clinic

24 Queen Anne Street

London

United Kingdom

W1G 9AX

Study participating centre

Southampton University Hospital

Southampton General Hospital

Tremona Road

Southampton

United Kingdom

SO16 6YD

Study participating centre

Bristol Eye Hospital

Lower Maudlin Street

Bristol

United Kingdom

BS1 2LX

Study participating centre

Manchester Royal Eye Hospital

Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre

Moorfields Eye Hospital

162 City Road
London
United Kingdom
EC1V 2PD

Study participating centre

Oxford Eye Hospital

Level Lg1 John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre

Central Middlesex Hospital

Acton Lane
London
United Kingdom
NW10 7NS

Study participating centre

Adelaide Eye and Retina Centre

18 North Terrace
Adelaide
Australia
SA 5000

Study participating centre

Centre Hospitalier Universitaire de Liege Domaine Universitaire du Sart Tilman

Avenue de l'Hôpital 1

Leige
Belgium
4000

Study participating centre
Queen Elizabeth II - Health Sciences Centre
Halifax
Nova Scotia
Canada
-

Study participating centre
Inselspital
Universitätsspital Bern
Bern
Switzerland
-

Study participating centre
AXON Clinical s.r.o.
Prague
Czech Republic
-

Study participating centre
Universitätsklinikum Gießen
Klinik und Poliklinik für Augenheilkunde
Giessen
Germany
-

Study participating centre
University Hospital Of Copenhagen
Glostrup Hospital
Glostrup
Denmark
-

Study participating centre

Hosp. Dos Demaig

Barcelona

Spain

-

Study participating centre

Ganglion OrvosiKözpont

Pecs

Hungary

-

Study participating centre

Azienda Ospedaliera Università

Università Degli studi della Campania - LuigiVanvitelli

Napoli

Italy

-

Study participating centre

Amsterdam University Medical Centers

Amsterdam

Netherlands

-

Study participating centre

Specjalistyczny Ośrodek Okulistyczny Oculomedica

Bydgoszcz

Poland

-

Study participating centre

Chsj - Hosp. Saojoao

Porto

Portugal

-

Study participating centre

S:t Eriks Ogonsjukhus

Stockholm

Sweden

-

Study participating centre
Hacettepe University Hospital
Ankara
Türkiye

-

Study participating centre
Texas Retina Associates
Dallas
United States of America

-

Sponsor information

Organisation

Janssen (Netherlands)

Sponsor details

Archimedesweg 29
Leiden
Netherlands
2333CM
+31 71 524 2166
ClinicalTrialsEU@its.jnj.com

Sponsor type

Industry

Website

<https://www.janssen.com/netherlands/>

ROR

<https://ror.org/04cxegr21>

Funder(s)

Funder type

Industry

Funder Name

Janssen Research and Development

Alternative Name(s)

Janssen R&D, Janssen Research & Development, Janssen Research & Development, LLC, Janssen Research & Development LLC, Janssen Pharmaceutical Companies of Johnson & Johnson, Research & Development at Janssen, JRD, J&J PRD

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan

1. Peer reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Submission to regulatory authorities
6. Other
7. Study results will be available via publication in scientific journals, the Clintrials.gov and ISRCTN databases & presentation at scientific meetings. Results will be made available to participants via a Plain Language Summary a year after the end of the study. The summary will describe the results regardless of study outcome in language that is understandable to the general public. It will not contain individual participant results or personal information. A copy of the Summary will be provided to the REC.

Intention to publish date

15/07/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request through the Yale Open Data Access (YODA) Project site at yoda.yale.edu. The data sharing policy of the Janssen Pharmaceutical Companies of Johnson & Johnson is available at www.janssen.com/clinical-trials/transparency.

IPD sharing plan summary

Available on request