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

Submission date
04/03/2023

Recruitment status
No longer recruiting

Registration date
20/09/2023

Overall study status
Completed

Last Edited
26/10/2026

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 February 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

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
2022-500746-16

Integrated Research Application System (IRAS)
1006234

Central Portfolio Management System (CPMS)
53494

Protocol serial number
81201887MDG2001

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

Primary study design
Interventional

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

Study type(s)
Efficacy, Safety, Treatment

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.

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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:
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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

Phase
Phase II

Drug/device/biological/vaccine name(s)
JNJ-81201887 (AAVCAGsCD59)

Primary outcome(s)
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

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Previous primary outcome measure:

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

Key secondary outcome(s)
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

Completion date
23/02/2026

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 (>=) 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)

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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 mm2 to 17.5 mm2 (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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
305

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

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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
United Kingdom

England

Argentina

Australia

Belgium

Brazil

Canada

Denmark

Germany

Hungary

Italy

Mexico

Netherlands

Poland

Portugal

Spain

Sweden

Switzerland

Türkiye

Study participating centre
The Retina Clinic
24 Queen Anne Street
London
England
W1G 9AX

Study participating centre
Southampton University Hospital
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
Bristol Eye Hospital
Lower Maudlin Street
Bristol
England
BS1 2LX

Study participating centre
Manchester Royal Eye Hospital
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Moorfields Eye Hospital
162 City Road

London
England
EC1V 2PD

Study participating centre
Oxford Eye Hospital
Level Lg1 John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
Central Middlesex Hospital
Acton Lane
London
England
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
Glostrop
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)

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

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