ISRCTN15146958 https://doi.org/10.1186/ISRCTN15146958

A study of nipocalimab in adults with moderate to severe systemic lupus erythematosus

Submission date
15/01/2026

Recruitment status
Recruiting

Registration date
13/03/2026

Overall study status
Ongoing

Last Edited
26/10/2026

Condition category
Musculoskeletal 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
Systemic lupus erythematosus (SLE) is a long-term disease where the immune system mistakenly attacks its own healthy tissues, causing inflammation (swelling and redness) in various organs. SLE can often cause repeated kidney inflammation, which may lead to kidney failure. It can also result in serious health problems from treatments and, in some cases, death. Current treatments for SLE usually work by either managing the symptoms or suppressing the immune system. Therefore, there is a need for new treatment options that work better. Nipocalimab is a monoclonal antibody* that selectively blocks the immunoglobulin (IgG) binding site called the neonatal Fc receptor (FcRN), resulting in a decrease of circulating IgG, thus reducing the inflammatory immune response to the harmful IgG in the body. *Type of protein designed to recognise and attach to a specific target. In this study, researchers want to learn how well nipocalimab works in participants with moderate to severe SLE as compared to placebo.

Who can participate?
Participants aged 18 years to 75 years with moderate to severe SLE.

What does the study involve?
The study consists of:
1. Screening period (up to Week 6)
2. Double-blind treatment period (Week 0 to Week 52): Participants will be randomly assigned to either Arm A (nipocalimab) or Arm B (placebo).
3. Open-label long-term extension period (Week 52 to Week 156): Eligible participants will have an option to enter an open-label long-term extension period and receive nipocalimab.
4. Safety follow-up (Week 162): Participants will be followed up for their health.
Safety assessments include monitoring of adverse events (AEs), serious AEs, and blood tests. All side effects will be recorded until the study ends (approximately 3 years and 1 month).

What are the possible benefits and risks of participating?
There is no established benefit to participants of this study. Based on scientific theory, taking nipocalimab may improve systemic lupus erythematosus (SLE). However, this cannot be guaranteed because nipocalimab is still under investigation as a treatment. Participants may experience some benefit from participation in the study that is not due to receiving the study

drug but due to regular visits and assessments monitoring overall health. Participation may help other people with SLE in the future. In addition, all participants are allowed to continue standard-of-care background therapy.
Participants may have side effects from the drug 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 common potential risks are getting side effects such as infections caused due to decreased serum IgG concentrations, reduced effectiveness of routine vaccines due to decreased IgG, activation of latent virus due to decreased IgG, hypoalbuminemia (low levels of albumin, a blood protein), injection site reactions, hypersensitivity (allergic reactions), drug-drug interactions and an increase in cholesterol after administering the study drug. There are other, less frequent potential risks. The participant information sheet and informed consent (which is signed by every participant) include a detailed section outlining the potential risks to participating in the study.
Not all possible side effects and risks related to the study drug are known at this moment. During the study, the sponsor may learn new information about the study drug. The study doctor will tell participants as soon as possible about any new information that might make them change their mind about being in the study, such as new risks. To minimise 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 their 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-Cilag International NV (Netherlands)

When is the study starting and how long is it expected to run for?
March 2026 to February 2031

Who is funding the study?
Janssen-Cilag International NV (Netherlands)

Who is the main contact?
JanssenUKRegistryQueries@its.jnj.com

Contact information

Type(s)
Scientific

Contact name
None - Medical Information and Product Information Enquiry

Contact details
Janssen Research & Development (Janssen-Cilag Ltd), 20 Grenfell Road
Maidenhead
United Kingdom
SL6 1EH

+44 (0)800 731 8450
JanssenUKRegistryQueries@its.jnj.com

Type(s)
Principal investigator

Contact name
Prof Christopher Edwards

Contact details
Southampton General Hospital, Tremona Road
Southampton
United Kingdom
SO16 6YD

Additional identifiers

Clinical Trials Information System (CTIS)
2025-523552-31

Integrated Research Application System (IRAS)
1013215

Central Portfolio Management System (CPMS)
70921

Sponsor's protocol code number
80202135SLE3001

Study information

Scientific Title
A Phase III, randomised, double-blind, placebo-controlled, multicentre study of nipocalimab in adults with moderate to severe systemic lupus erythematosus (GARDENIA-SLE)

Acronym
GARDENIA-SLE

Study objectives
Primary objective:
To evaluate how well nipocalimab works in participants with moderate to severe Systemic Lupus Erythematosus (SLE) as compared to placebo.

Secondary objective:
To further evaluate how well nipocalimab works as compared to placebo in participants with moderate to severe SLE.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/03/2026, West of Scotland REC 1 (West of Scotland Research Ethics Service Admin Building, Level 2 Gartnavel Royal Hospital 1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; -; ggc.wosrec1@nhs.scot), ref: 26/WS/0012

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment, Safety

Study type(s)
Efficacy, Safety, Treatment, Other

Health condition(s) or problem(s) studied
Systemic lupus erythematosus

Interventions
Experimental: Nipocalimab
Participants will receive nipocalimab up to Week 52 in the double-blind treatment period along with standard of care treatments. At Week 52, eligible participants will have the option to enter an open-label long-term extension (OLE) period, where they will continue to receive nipocalimab until Week 156 or until the study intervention is discontinued.

Placebo Comparator: Placebo
Participants will receive a placebo up to Week 52 in the double-blind treatment period along with standard of care treatment. At Week 52, eligible participants will have the option to enter an open-label extension period, where they will continue to receive nipocalimab until Week 156 or until the study intervention is discontinued.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Nipocalimab

Primary outcome(s)

Percentage of participants achieving Systemic Lupus Erythematosus (SLE) Responder Index (SRI) -4 composite
response at Week 52 (end of the double-blind treatment period). The SLE SRI-4 composite response is a composite response of at least a 4 point reduction in SLE Disease Activity Index 2000 (SLEDAI-2K), no British Isles Lupus Assessment Group-2004 (BILAG-2004) worsening, defined as no new A or less than or equal to 1 new B items compared to baseline and no worsening in Physician's Global Assessment (PGA) (which is defined as a 10% or more increase compared to baseline).

Key secondary outcome(s)

1. Percentage of participants achieving an SLE SRI-4 composite response at Week 52 with a high baseline IFN gene signature ('Interferon [IFN] high'). The SLE SRI-4 composite response is a composite response of at least a 4-point reduction in SLEDAI-2K, no BILAG-2004 worsening, defined as no new A or 1 or fewer new B items compared to baseline and no worsening in PGA (more than 10% increase from baseline). 'IFN high' is defined as an elevated peripheral type 1 IFN gene signature at baseline.
2. Percentage of participants achieving SRI-4 composite response at Week 52 with a sustained reduction in oral glucocorticoid (GC) dose. A sustained reduction in oral GC dose at Week 52 is defined as achieving less than or equal to 5 mg/day oral prednisone (or equivalent) AND no increase in that dose from Week 32 until Week 52.
3. Percentage of participants who achieve Lupus Low Disease Activity State (LLDAS) at Week 52. LLDAS is defined as follows:
SLEDAI-2K of 4 or less with no activity in the major organ systems (renal, central nervous system, cardiopulmonary, vasculitis, fever) and no haemolytic anaemia or gastrointestinal activity measured as maintaining a 'D' (no disease activity but suggests the system had previously been affected) or 'E' (no current or previous disease activity) score in BILAG gastrointestinal body system; no new lupus disease activity compared to the previous assessment measured as no new or worsening individual BILAG parameters; physician's global assessment of disease activity of one or less on a three-point visual analogue scale from no disease activity to severe disease activity; a current prednisolone (or equivalent) dose of 7.5 mg or less daily and well-tolerated standard maintenance doses of immunosuppressive drugs and approved biological agents.
4. Percentage of participants with two or fewer active joints at Week 52 in participants with two or more active joints at baseline. Percentage of participants with <2 active joints at Week 52 in participants with >=2 active joints at baseline will be
reported.
5. Change from baseline in the Lupus Symptoms Joint Pain Score at Week 52. Lupus symptoms joint pain score at Week 52 will be reported.
6. Percentage of participants achieving sustained reduction in oral glucocorticoid dose at Week 52 in participants treated with oral glucocorticoids of more than 5 mg/day prednisone (or equivalent) at baseline. Percentage of participants achieving sustained reduction in oral glucocorticoid dose at Week 52 in participants treated with oral
glucocorticoid >5 mg/day prednisone (or equivalent) at baseline will be reported.
7. Change from baseline in Functional Assessment of Chronic Illness Therapy Fatigue (FACIT) Fatigue Score at Week 52. FACIT-Fatigue version 4.0 is a 13-item questionnaire that assesses participant-reported fatigue and its impact upon daily activities and function over the past 7 days. Participants will be asked to answer each question using a 5-point Likert scale (0 = Not at all; 1 = A little bit; 2 = Somewhat; 3 = Quite a bit; and 4 = Very much). FACIT-Fatigue has a total score range from 0 to 52, with 0 being the worst possible score and 52 the best.
8. Percentage of participants with BILAG flare-free status up until Week 52. A participant has a flare-free status if no flare has been reported during the 52-week treatment period. A flare is

defined as either one or more new BILAG-2004 A (severe disease activity) or two or more new BILAG-2004 B (moderate disease activity) items compared to the previous visit.
9. Percentage of participants achieving SRI-4 composite response at Week 52 with high baseline autoantibodies ('Autoantibody High'). 'Autoantibody high' participants are defined as participants with high autoantibody levels at baseline.

Completion date
21/02/2031

Eligibility

Key inclusion criteria
Current inclusion criteria as of 01/09/2026:
1. Aged 18 to 75 years old
2. Male or female
3. Medically stable on the basis of physical examination, medical history, vital signs and a 12-lead electrocardiogram (ECG) performed at screening
4. A clinical diagnosis of systemic lupus erythematosus (SLE) for more than or equal to 24 weeks before screening and meeting the European League Against Rheumatism/American College of Rheumatology (EULAR/ACR) Classification Criteria.
5. Participants must have a Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score greater than or equal to 6 and a Clinical SLEDAI-2K greater than or equal to 4 at screening, AND a clinical SLEDAI-2K score greater than or equal to 4 points at Week 0. For eligibility, points attributed to "lupus headache," "alopecia," and "organic brain syndrome" are excluded.
6. Participants of childbearing potential must have a negative serum beta human chorionic gonadotropin (β-hCG) test at screening and a negative urine (β- hCG) test at Week 0 before randomisation
7. Participants must have at least one BILAG#2004 (British Isles Lupus Assessment Group#2004) A score or two BILAG#2004 B scores observed at screening

Previous inclusion criteria:
1. Aged 18 to 75 years old
2. Male or female
3. Medically stable on the basis of physical examination, medical history, vital signs and a 12-lead electrocardiogram (ECG) performed at screening
4. A clinical diagnosis of systemic lupus erythematosus (SLE) for more than or equal to 24 weeks before screening. This diagnosis should be made according to the European League Against Rheumatism/American College of Rheumatology (EULAR/ACR) Classification Criteria.
5. Participants must have a Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score greater than or equal to 6 and a Clinical SLEDAI-2K greater than or equal to 4 at screening, AND a clinical SLEDAI-2K score greater than or equal to 4 points at Week 0, excluding points attributed to "lupus headache," "alopecia," and "organic brain syndrome".
6. Participants of childbearing potential must have a negative serum beta human chorionic gonadotropin (β-hCG) test at screening and a negative urine (β- hCG) test at Week 0 before randomisation
7. Participants must have at least one BILAG#2004 (British Isles Lupus Assessment Group#2004) A score or two BILAG#2004 B scores observed at screening

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. History of severe, progressive and/or uncontrolled hepatic, gastrointestinal, renal, pulmonary, cardiovascular, psychiatric, neurological or musculoskeletal disorder, hypertension, and/or any other medical or uncontrolled autoimmune disorder (s) or clinically significant abnormalities in screening laboratory tests
2. Any unstable or progressive manifestation of SLE that is likely to warrant escalation in therapy beyond permitted background medications
3. Confirmed or suspected clinical immunodeficiency syndrome not related to treatment of SLE or has a family history of congenital or hereditary immunodeficiency unless confirmed absent in the participant
4. Has shown a previous severe immediate hypersensitivity reaction, such as anaphylaxis, to therapeutic proteins
5. Suspected or known allergies, hypersensitivity, or intolerance to nipocalimab or its excipients, or excipients used in the placebo formulation

Date of first enrolment
06/03/2026

Date of final enrolment
27/10/2027

Locations

Countries of recruitment
United Kingdom

England

Argentina

Australia

Brazil

Bulgaria

China

Colombia

Czech Republic

Denmark

Finland

France

Georgia

Germany

Greece

Hungary

Israel

Italy

Japan

Korea, South

Malaysia

Mexico

Norway

Poland

Portugal

Romania

Serbia

Slovakia

South Africa

Spain

Switzerland

Taiwan

Thailand

Türkiye

United States of America

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
Bretton Gate
Bretton
Peterborough
England
PE3 9GZ

Study participating centre
Great Western Hospitals NHS Foundation Trust
Great Western Hospital
Marlborough Road
Swindon
England
SN3 6BB

Study participating centre
Guy's Hospital
Great Maze Pond
London
England
SE1 9RT

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

Study participating centre
Haywood Hospital
High Lane

Stoke-on-trent
England
ST6 7AG

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre
Royal United Hospital
Combe Park
Bath
England
BA1 3NG

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

Sponsor information

Organisation
Janssen-Cilag International NV

Funder(s)

Funder type

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 data sharing policy of the Janssen Pharmaceutical Companies of Johnson & Johnson is available at https://www.janssen.com/clinicaltrials/transparency. As noted on this site, requests for access to the study data can be submitted through the Yale Open Data Access (YODA) Project site at yoda.yale.edu.

IPD sharing plan summary
Available on request