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A study comparing talquetamab in combination with daratumumab or in combination with daratumumab and pomalidomide versus daratumumab in combination with pomalidomide and dexamethasone in participants with multiple myeloma that returns after treatment or is resistant to treatment

Submission date 26/10/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 09/02/2023	**Overall study status** Ongoing	
Last Edited 05/08/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Multiple myeloma is a blood cancer that affects certain types of white blood cells called plasma cells. Although treatments are available, multiple myeloma can come back after treatment or be resistant to standard treatment. Drugs that induce the body's T cells (a type of white blood cell) to attack cancer cells may be an effective way to destroy cancer cells. Talquetamab (JNJ-64407564) is a modified antibody that binds to T cells and myeloma cells. Talquetamab activates the T cells, which leads to the killing of myeloma cells. In this study, the researchers want to study whether Tal-DP and Tal-D keep the participants' cancer from getting worse for a longer period compared to DPd.

Who can participate?
Patients aged 18 years or older with multiple myeloma that has either come back after treatment or is resistant to standard treatment, who have received at least one prior anticancer therapy

What does the study involve?
The study will be conducted as:
1. Screening (28 days)
2. Treatment phase: participants will receive one of three treatments in a 28-day cycle:
2.1. Talquetamab subcutaneous (SC; as an injection under skin) in combination with daratumumab subcutaneous (SC; as an injection under skin) and pomalidomide (Tal-DP) orally
2.2. Daratumumab SC in combination with pomalidomide orally and dexamethasone (DPd) either

orally or as an injection in the veins
2.3. Talquetamab SC in combination with daratumumab SC (Tal-D)
3. Posttreatment follow-up phase: participants will be followed up for safety until death, withdrawal of consent, or end of the study, whichever occurs first
During the study, some tests will be performed, such as blood tests, physical and neurologic examinations, vital signs, Eastern Cooperative Oncology Group (ECOG) performance status and questionnaires. Blood samples will be taken at multiple timepoints to see how the body responds to treatment. Disease status will be checked based on International Myeloma Working Group (IMWG) criteria for multiple myeloma. Side effects will be recorded until the study ends (up to 6 years 6 months).

What are the possible benefits and risks of participating?
Based on scientific theory, taking talquetamab may improve multiple myeloma. However, this cannot be guaranteed because talquetamab is still under investigation as a treatment and it is not known whether talquetamab will work.
Participants may experience some benefit from participation in the study that is not due to receiving talquetamab, but rather is due to regular visits and assessments monitoring overall health. Participation in the study may help other people with multiple myeloma in the future.
Participants may have side effects from the drug(s) or procedures used in this study that may be mild to severe and even life-threatening, and they can vary from person to person. The most common, known risks are getting symptoms such as cytokine release syndrome (CRS), cytopenias, skin and nail changes, oral side-effects, infection, injection-site reactions, and increased risk for immune effector cell-associated neurotoxicity syndrome (ICANS). 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 talquetamab are known at this moment. During the study, the sponsor may learn new information about talquetamab. 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 looked at and asked about 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 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 (for example, 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?
January 2021 to September 2029

Who is funding the study?
Janssen (Netherlands)

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

Contact information

Type(s)
Scientific

Contact name
Dr Ertugrul Celebi

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Type(s)
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Additional identifiers

EudraCT/CTIS number
2021-000202-22

IRAS number
1006071

ClinicalTrials.gov number

NCT05455320

Secondary identifying numbers
64407564MMY3002, IRAS 1006071, CPMS 52938

Study information

Scientific Title
A Phase III randomized study comparing talquetamab in combination with daratumumab (SC) and pomalidomide (Tal-DP) or talquetamab (SC) in combination with daratumumab SC (Tal-D) versus daratumumab SC, pomalidomide and dexamethasone (DPd), in participants with relapsed or refractory multiple myeloma who have received at least one prior line of therapy

Acronym
MonumenTAL-3

Study objectives
The overall rationale of the study is that combination treatments of talquetamab, daratumumab, pomalidomide and dexamethasone may lead to enhanced clinical responses in treatment of relapsed or refractory multiple myeloma through multiple mechanisms of action.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/01/2023, West Midlands - Edgbaston Research Ethics Committee (3rd Floor Barlow House, Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 207 104 8357; edgbaston.rec@hra.nhs.uk), ref: 22/WM/0261

Study design
Randomized controlled open trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Relapsed or refractory multiple myeloma

Interventions

Central randomisation will be implemented in this study. Participants will be randomly assigned to one of three treatment arms based on a computer-generated randomisation schedule prepared before the study by or under the supervision of the sponsor.

Experimental: Arm A: Talquetamab Subcutaneous (SC) in Combination With Daratumumab SC and Pomalidomide (Tal-DP)
Participants will receive talquetamab and daratumumab as SC injections; pomalidomide will be self-administered as a single dose orally; dexamethasone may be given orally or intravenously as a pretreatment medication and study drug.

Drug: Talquetamab
Talquetamab will be administered subcutaneously.
Other Name: JNJ-64407564

Drug: Daratumumab
Daratumumab will be administered subcutaneously.

Drug: Pomalidomide
Pomalidomide will be administered orally.

Drug: Dexamethasone
Dexamethasone will be administered orally or intravenously.

Experimental: Arm B: Daratumumab in Combination With Pomalidomide and Dexamethasone (DPd)
Participants will receive daratumumab as an SC injection; pomalidomide will be self-administered as a single dose orally; dexamethasone may be given orally or intravenously as a pretreatment medication and study drug.

Drug: Daratumumab
Daratumumab will be administered subcutaneously.

Drug: Pomalidomide
Pomalidomide will be administered orally.

Drug: Dexamethasone
Dexamethasone will be administered orally or intravenously

Experimental: Arm C: Talquetamab SC in Combination With Daratumumab SC (Tal-D)
Participants will receive talquetamab and daratumumab as injection SC injections; dexamethasone may be given orally or intravenously as a pretreatment medication and study drug.

Drug: Talquetamab
Talquetamab will be administered subcutaneously.
Other Name: JNJ-64407564

Drug: Daratumumab
Daratumumab will be administered subcutaneously.

Drug: Dexamethasone
Dexamethasone will be administered orally or intravenously.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Talquetamab, daratumumab, pomalidomide, dexamethasone

Primary outcome measure
Progression-free survival (PFS), defined as the time interval between the date of randomisation to the date of either disease progression or death due to any cause, whichever comes first, measured up to 6 years 6 months.

Secondary outcome measures
Current secondary outcome measures as of 07/11/2023:

1. Overall response (partial response [PR] or better), defined as the percentage of participants who have a PR or better according to International Myeloma Working Group (IMWG) criteria, measured up to 6 years 6 months.
2. Very good partial response (VGPR) or better rate, defined as the percentage of participants who achieve a VGPR or better according to IMWG response criteria, measured up to 6 years 6 months.
3. Complete response (CR) or better rate, defined as the percentage of participants who achieve CR or better according to IMWG response criteria, measured up to 6 years 6 months.
4. Overall minimal residual disease (MRD) negative status, defined as a proportion of participants who achieve MRD negativity (at a threshold of 10^-5), at any timepoint after the first dose of the study drug and before disease progression or the start of subsequent antimyeloma therapy, measured up to 6 years 6 months.
5. Overall survival (OS), defined as the time from the date of randomisation to the date of the participant's death, measured up to 6 years 6 months.
6. Progression-free survival on next-line therapy (PFS2), defined as the time interval between the date of randomisation and the date of the event, which is defined as progressive disease as assessed by the investigator on the first subsequent line of antimyeloma therapy, or death from any cause, whichever occurs first, measured up to 6 years 6 months.
7. Time to next therapy (TTNT), defined as the time from randomisation to the start of subsequent antimyeloma treatment, measured up to 6 years 6 months.
8. Number of participants with adverse events (AEs), which is any untoward medical occurrence in a participant participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study, measured up to 6 years 6 months.
9. Number of participants with AEs by severity, where severity will be graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), measured up to 6 years 6 months.
10. Serum concentrations of talquetamab, measured using an electrochemiluminescence-based immunoassay (ECLIA) up to 6 years 6 months
11. Serum concentrations of daratumumab, measured using an electrochemiluminescence-based immunoassay (ECLIA) up to 6 years 6 months

12. Number of participants with the presence of anti-drug antibodies (ADAs) to talquetamab, measured using an electrochemiluminescence-based immunoassay (ECLIA) up to 6 years 6 months
13. Number of participants with the presence of anti-drug antibodies (ADAs) to daratumumab, measured using an electrochemiluminescence-based immunoassay (ECLIA) up to 6 years 6 months
14. Time to worsening in symptoms, functioning, and overall health-related quality of life (HRQoL) as assessed by multiple myeloma symptom and impact questionnaire (MySIm-Q), a disease-specific patient-reported outcome (PRO) assessment complementary to the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core-30 item (EORTC-QLQ-C30), measured up to 6 years 6 months.
15. Time to worsening in symptoms, functioning, and HRQoL as assessed by PROMIS Short Form Version 2.0 –Physical Functioning 8c, an 8-item fixed-length short form derived from the PROMIS Physical Function item bank, measured up to 6 years 6 months.
16. Time to worsening in symptoms, functioning, and HRQoL as assessed by EORTC-QLQ-C30, measured up to 6 years 6 months.
17. Time to worsening in symptoms, functioning, and HRQoL as assessed by PRO-CTCAE, an item library of common AEs experienced by people with cancer that are appropriate for self-reporting of treatment tolerability, measured up to 6 years 6 months.
18. Time to worsening in symptoms, functioning, and HRQoL as assessed by EuroQol Five Dimension Questionnaire 5-Level (EQ-5D-5L) a generic measure of health status. For purposes of this study, the EQ-5D-5L will be used to generate utility scores for use in cost-effectiveness analyses, measured up to 6 years 6 months.
19. Time to worsening in symptoms, functioning, and HRQoL as assessed by Patient Global Impression - Severity (PGI-S) which will be used as an anchor, external criterion, to determine meaningful change in scores for the MySIm-Q and PROMIS SF PF 8c in this population, measured up to 6 years 6 months.
20. Change from baseline in symptoms, functioning, and overall HRQoL as assessed by Multiple Myeloma Symptom and Impact Questionnaire (MySIm-Q), a disease-specific PRO assessment complementary to the EORTC-QLQ-C30, measured from baseline up to 6 years 6 months.
21. Change from baseline in symptoms, functioning, and HRQoL as assessed by PROMIS Short Form Version 2.0 –Physical Functioning 8c, an 8-item fixed-length short form derived from the PROMIS Physical Function item bank, measured from baseline up to 6 years 6 months.
22. Change from baseline in symptoms, functioning, and HRQoL as assessed by EORTC-QLQ-C30, measured from baseline up to 6 years 6 months.
23. Change from baseline in symptoms, functioning, and HRQoL as assessed by PRO-CTCAE an item library of common AEs experienced by people with cancer that are appropriate for self-reporting of treatment tolerability, measured from baseline up to 6 years 6 months.
24. Change from baseline in symptoms, functioning, and HRQoL as assessed by EuroQol Five Dimension Questionnaire 5-Level (EQ-5D-5L) a generic measure of health status. For purposes of this study, the EQ-5D-5L will be used to generate utility scores for use in cost-effectiveness analyses, measured from baseline up to 6 years 6 months.
25. Change from baseline in symptoms, functioning, and HRQoL as assessed by Patient Global Impression - Severity (PGI-S), which will be used as an anchor, external criterion, to determine meaningful change in scores for the MySIm-Q and PROMIS SF PF 8c in this population, measured from baseline up to 6 years 6 months.

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Previous secondary outcome measures:

1. Overall response (partial response [PR] or better), defined as the percentage of participants who have a PR or better according to International Myeloma Working Group (IMWG) criteria, measured up to 6 years 6 months.
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3. Complete response (CR) or better rate, defined as the percentage of participants who achieve CR or better according to IMWG response criteria, measured up to 6 years 6 months.
4. Overall minimal residual disease (MRD) negative status, defined as the percentage of participants who achieve MRD negativity (at a threshold of 10^-5), at any timepoint after the first dose of the study drug and before disease progression or the start of subsequent antimyeloma therapy, measured up to 6 years 6 months.
5. Overall survival (OS), defined as the time from the date of the first dose of the study drug to the date of the participant's death, measured up to 6 years 6 months.
6. Progression-free survival on next-line therapy (PFS2), defined as the time interval between the date of the first dose of the study drug and the date of the event, which is defined as progressive disease as assessed by the investigator on the first subsequent line of antimyeloma therapy, or death from any cause, whichever occurs first, measured up to 6 years 6 months.
7. Time to next therapy (TTNT), defined as the time from the first dose of the study drug to the start of subsequent antimyeloma treatment, measured up to 6 years 6 months.
8. Number of participants with adverse events (AEs), which is any untoward medical occurrence in a participant participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study, measured up to 6 years 6 months.
9. Number of participants with AEs by severity, where severity will be graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), measured up to 6 years 6 months.
10. Serum concentrations of talquetamab, measured using an electrochemiluminescence-based immunoassay (ECLIA) up to 6 years 6 months
11. Number of participants with the presence of anti-drug antibodies (ADAs) to talquetamab, measured using an electrochemiluminescence-based immunoassay (ECLIA) up to 6 years 6 months
12. Number of participants with the presence of anti-drug antibodies (ADAs) to daratumumab, measured using an electrochemiluminescence-based immunoassay (ECLIA) up to 6 years 6 months
13. Time to worsening in symptoms, functioning, and overall health-related quality of life (HRQoL) as assessed by multiple myeloma symptom and impact questionnaire (MySIm-Q), a disease-specific patient-reported outcome (PRO) assessment complementary to the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core-30 item (EORTC-QLQ-C30), measured up to 6 years 6 months.
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18. Time to worsening in symptoms, functioning, and HRQoL as assessed by Patient Global Impression - Severity (PGI-S) which will be used as an anchor, external criterion, to determine meaningful change in scores for the MySIm-Q and PROMIS SF PF 8c in this population, measured up to 6 years 6 months.
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21. Change from baseline in symptoms, functioning, and HRQoL as assessed by EORTC-QLQ-C30, measured from baseline up to 6 years 6 months.
22. Change from baseline in symptoms, functioning, and HRQoL as assessed by PRO-CTCAE an item library of common AEs experienced by people with cancer that are appropriate for self-reporting of treatment tolerability, measured from baseline up to 6 years 6 months.
23. Change from baseline in symptoms, functioning, and HRQoL as assessed by EuroQol Five Dimension Questionnaire 5-Level (EQ-5D-5L) a generic measure of health status. For purposes of this study, the EQ-5D-5L will be used to generate utility scores for use in cost-effectiveness analyses, measured from baseline up to 6 years 6 months.
24. Change from baseline in symptoms, functioning, and HRQoL as assessed by Patient Global Impression - Severity (PGI-S), which will be used as an anchor, external criterion, to determine meaningful change in scores for the MySIm-Q and PROMIS SF PF 8c in this population, measured from baseline up to 6 years 6 months.

Overall study start date
13/01/2021

Completion date
30/09/2029

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/05/2024:

1. Documented multiple myeloma as defined:
1.1. Multiple myeloma diagnosis according to the International Myeloma Working Group (IMWG) diagnostic criteria
1.2. Measurable disease at screening as defined by any of the following:
1.2.1. Serum M-protein level ≥0.5 g/dL (central laboratory)
1.2.2. Urine M-protein level ≥200 mg/24 hours (central laboratory)
1.2.3. Light chain multiple myeloma without measurable M-protein in the serum or the urine: serum immunoglobulin free light chain ≥10 mg/dL (central laboratory), and abnormal serum immunoglobulin kappa lambda free light chain ratio
2. Relapsed or refractory disease as defined by:
2.1. Relapsed disease is defined as an initial response to prior treatment, followed by confirmed progressive disease by IMWG criteria greater than (>) 60 days after cessation of treatment
2.2. Refractory disease is defined as less than (<) 25% reduction in monoclonal paraprotein (M-protein) or confirmed progressive disease by IMWG criteria during previous treatment or less than or equal to (<=) 60 days after cessation of treatment

3. Received at least one prior line of antimyeloma therapy including a proteasome inhibitor (PI) and lenalidomide. Participants who have received only one prior line of antimyeloma therapy must be considered lenalidomide-refractory (that is, have demonstrated progressive disease by IMWG criteria on or within 60 days of completion of lenalidomide-containing regimen). Participants who have received ≥2 prior lines of antimyeloma therapy must be considered lenalidomide exposed
4. Documented evidence of progressive disease based on the investigator's determination of response by the IMWG criteria on or after their last regimen
5. Have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1, or 2 at screening and immediately prior to the start of administration of study treatment

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1.1. Multiple myeloma diagnosis according to the International Myeloma Working Group (IMWG) diagnostic criteria
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1.2.1. Serum M-protein level ≥0.5 g/dL (central laboratory)
1.2.2. Urine M-protein level ≥200 mg/24 hours (central laboratory)
1.2.3. Light chain multiple myeloma without measurable M-protein in the serum or the urine: serum immunoglobulin free light chain ≥10 mg/dL (central laboratory), and abnormal serum immunoglobulin kappa lambda free light chain ratio
2. Relapsed or refractory disease as defined:
2.1. Relapsed disease is defined as an initial response to prior treatment, followed by confirmed progressive disease by IMWG criteria >60 days after cessation of treatment
2.2. Refractory disease is defined as <25% reduction in monoclonal paraprotein (M-protein) or confirmed progressive disease by IMWG criteria during previous treatment or less than or equal to 60 days after cessation of treatment
3. Received at least one prior line of antimyeloma therapy including a proteasome inhibitor (PI) and lenalidomide. Participants who have received only one prior line of antimyeloma therapy must be considered lenalidomide-refractory (that is, have demonstrated progressive disease by IMWG criteria on or within 60 days of completion of lenalidomide-containing regimen). Participants who have received ≥2 prior lines of antimyeloma therapy must be considered lenalidomide exposed
4. Documented evidence of progressive disease based on the investigator's determination of response by the IMWG criteria on or after their last regimen
5. Have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1, or 2 at screening and immediately prior to the start of administration of study treatment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

810

Total final enrolment
864

Key exclusion criteria
Current exclusion criteria as of 20/05/2024:

1. Contraindications or life-threatening allergies, hypersensitivity, or intolerance to study drug excipients
2. Disease is considered refractory to an anti-cluster of differentiation 38 (CD38) monoclonal antibody as defined per IMWG consensus guidelines (progression during treatment or within 60 days of completing therapy with an anti-CD38 monoclonal antibody)
3. Received prior pomalidomide therapy
4. A maximum cumulative dose of corticosteroids to ≥140 mg of prednisone or equivalent within the 14-day period before the first dose of the study drug
5. Known active central nervous system (CNS) involvement or exhibits clinical signs of meningeal involvement of multiple myeloma. If either is suspected, negative whole-brain magnetic resonance imaging (MRI) and lumbar cytology are required
6. Plasma cell leukaemia (per IMWG criteria) at the time of screening, Waldenström's macroglobulinemia, polyneuropathy, organomegaly, endocrinopathy, M-protein, and skin changes (POEMS syndrome), or primary amyloid light chain amyloidosis

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Previous exclusion criteria as of 07/11/2023:

1. Contraindications or life-threatening allergies, hypersensitivity, or intolerance to study drug excipients
2. Disease is considered refractory to an anti-cluster of differentiation 38 (CD38) monoclonal antibody as defined per IMWG consensus guidelines (progression during treatment or within 60 days of completing therapy with an anti-CD38 monoclonal antibody)
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4. Known active central nervous system (CNS) involvement or exhibits clinical signs of meningeal involvement of multiple myeloma. If either is suspected, negative whole-brain magnetic resonance imaging (MRI) and lumbar cytology are required
5. Plasma cell leukaemia at the time of screening, Waldenström's macroglobulinemia, polyneuropathy, organomegaly, endocrinopathy, M-protein, and skin changes (POEMS syndrome), or primary amyloid light chain amyloidosis

Date of first enrolment
13/10/2022

Date of final enrolment
29/03/2024

Locations

Countries of recruitment
Belgium

Brazil

China

Czech Republic

England

France

Germany

Greece

Israel

Italy

Japan

Korea, South

Netherlands

Poland

Spain

Taiwan

Türkiye

United Kingdom

United States of America

Study participating centre
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Janssen (Netherlands)

Sponsor details
Archimedesweg 29
Leiden
Netherlands
2333 CM
+31 (0)71 524 21 06
ClinicalTrialsEU@its.jnj.com

Sponsor type
Industry

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

Study results will be available via publication in scientific journals, the EudraCT database and 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 the study outcome in language that is understandable to the general public. It will not contain individual participant results or their personal information. A copy of the Summary will be provided to the REC.

Intention to publish date
06/04/2030

Individual participant data (IPD) sharing plan
The data sharing policy of the Janssen Pharmaceutical Companies of Johnson and Johnson is available at https://www.janssen.com/clinical-trials/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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No