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A study to characterize nicotine delivery of the JUUL2 electronic nicotine delivery system in adults as compared to a commercially available e-cigarette and combustible cigarette

Submission date
23/10/2024

Recruitment status
No longer recruiting

Registration date
25/10/2024

Overall study status
Completed

Last Edited
25/10/2024

Condition category
Other

[_] 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
While recent surveys have shown that the prevalence of cigarette smoking has reached a historic low of 11.5% in the United States (US), millions of Americans continue to smoke despite overwhelming scientific evidence demonstrating negative health consequences. Additionally, cigarette smoking continues to be a leading cause of preventable death in the US. However, in 2015, nearly 70% of American adult smokers reported wanting to quit smoking, and though 55% had attempted a quit attempt within the previous year, only 7.4% reported having recently stopped smoking. These data exemplify the difficulty that smokers face when trying to quit. The US Food and Drug Administration (FDA) proposed to implement a comprehensive approach to nicotine product regulation to reduce the impact of the harms associated with cigarette smoking. Within such a harm reduction framework, alternate forms of nicotine delivery that do not subject consumers to the toxic chemicals found in combustible cigarette smoke may play a critical role. To this end, the JUUL® Electronic Nicotine Delivery System (ENDS) has been developed as an alternative to combustible cigarettes for adult smokers.

The JUUL2 Device and pods comprise an ENDS product that is currently being marketed in the United Kingdom to adult smokers as an alternative to combustible cigarettes. The JUUL2 ENDS design is that of a typical ENDS product described above. However, JUUL2 ENDS products do not contain tobacco leaf, and product data to date indicate JUUL2 ENDS use has demonstrated the production of significantly lower levels of chemicals identified by the FDA as harmful /potentially harmful constituents (HPHCs) compared to combustible cigarettes
The purpose of this study is to characterize the pharmacokinetic (PK) profile of plasma nicotine for a third-generation JUUL ENDS device, and two flavor pods (JUUL2 Virginia Tobacco and Fresh Menthol, containing 3% and 5% nicotine) compared to a commercially available NJOY Ace with a commercially available pod containing 5.0% nicotine and the subject's commercially available usual brand (UB) of a combustible cigarette. Subjective effects will also be assessed to gain an understanding of nicotine withdrawal and dependence, satisfying and reinforcing effects.

Who can participate?
Adult healthy volunteer smokers aged between 22 and 65 years old who smoke at least 10 manufactured combustible cigarettes per day. Subjects must also be experienced in using e-cigarettes.

What does the study involve?
Subjects will complete screening procedures including laboratory tests to ensure subject safety and eligibility. After completing screening procedures, subjects will be checked into a clinic for 5 days/4 nights. Subjects will be trained on how to complete the subjective assessments and questionnaires. They will be allowed to smoke their US of cigarettes for a 4-hour period ad libitum, ending approximately 12 hours prior to study product use on Day 1. On Study Days 2-4, subjects will be given their assigned study product for two product use sessions each day. The study days include a controlled product use session (10 puffs, 3 seconds long, taken every 30 seconds), 4 hours of abstinence from nicotine, and then a 5-minute ad libitum session with the same study product. Before, during, and after both product use sessions, blood samples will be collected at predetermined time points to assess plasma nicotine PK parameters (nicotine uptake), and subjects will complete subjective effects questionnaires at predetermined time points during each product use session (after collection of any coincident blood sample for nicotine analysis). Subjects will be discharged after study procedures on Day 5. A follow-up phone call with subjects will be made approximately 7 days after the subject's last study day. Subjects will have completed the study following the 7-day FU phone call.

What are the possible benefits and risks of participating?
Participants are not likely to receive any direct benefit from taking part in the study. Products used in this study contain nicotine which is a highly addictive substance. There is a remote chance that the study product may cause an allergic reaction, which in some cases may be severe. Symptoms include sudden shortness of breath, decreased consciousness and rash. Some of the most likely health risks or adverse events/experiences of participation include:
1. Mouth, tongue, and gum irritation
2. Throat irritation
3. Coughing
4. Headache
5. Dizziness
6. Feeling ill (or nauseated)
7. Vomiting
8. Abdominal pain
9. Diarrhea

In addition to the health risks listed above, there may be unknown, infrequent, and/or unforeseeable health risks associated with the use of the study product, including severe or life-threatening reactions or unexpected interactions with another medication. These symptoms may include:
1. Trouble breathing
2. Swelling of face, tongue or throat
3. Rash
4. Flushing
5. Itching
6. Sneezing or runny nose
7. Light-headedness or fainting
8. Irregular or racing heart rate
9. The JUUL2 System should be kept at least 15.3 cm away from pacemakers and other sensitive medical equipment
10. ENDS and e-cigarette product use may aggravate pre-existing lung or heart conditions

11. Nicotine over-dosage symptoms may include vomiting, diarrhea, nausea, dizziness, increased saliva, abdominal pain, headache, weakness, or rapid heartbeat
12. Injuries, such as burns, from ENDS product malfunctions have occurred. The potential exposures from participating in this study are not anticipated to result in an overall increase in long-term health risks as compared to the health risks from your current tobacco product use, but the full extent of long-term health risks associated with the use of ENDS products are not yet known.
All combustible cigarette smokers are at increased risk for:
1. Heart disease
2. Lung cancer
3. Increased risk of other types of cancer
4. Chronic Obstructive Pulmonary Disease (COPD)
5. Premature death
Female smokers are also at increased risk for:
1. Cancer of the cervix
2. Problems with periods (menstrual problems)
3. Problems getting pregnant (fertility problems)
4. Premature delivery
5. Having a low-birth-weight baby
Male smokers are also at increased risk for:
1. Problems with erections (impotence/erectile dysfunction) Risks associated with study procedures:
2. Blood drawing (venipuncture) risks: drawing blood may cause temporary discomfort from the needle stick, bleeding, bruising, infection, and fainting
3. Electrocardiogram (ECG) risks: the ECG involves placing electrodes on the skin. You may experience an allergic reaction to the adhesive used to attach the electrodes to the skin. These symptoms are generally mild and clear up on their own.
4. HIV and hepatitis testing risks: being tested for HIV and hepatitis may cause anxiety regardless of the test results.

Where is the study run from?
Juul Labs Inc. (USA)

When is the study starting and how long is it expected to run for?
October 2024 to January 2025

Who is funding the study?
Juul Labs Inc. (USA)

Who is the main contact?
Sandra Miller, sandra.miller@juul.com

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Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
JLI-24-03

Study information

Scientific Title
A two-part, randomized, controlled, crossover study to characterize nicotine pharmacokinetics of the JUUL2 Electronic Nicotine Delivery System (ENDS), in two flavors and two nicotine strengths, compared to a commercially available ENDS product and the subjects' usual brand of combustible cigarette

Acronym
PK3/5%

Study objectives
The purpose of this study is to characterize the PK profile of plasma nicotine for a JUUL Electronic Nicotine Delivery System (ENDS) Device, two e-liquid flavors, and two nicotine

strengths pods (JUUL2 ENDS Devices with JUUL2 pods, Virginia Tobacco or Fresh Menthol flavors, at 3% and 5% nicotine) compared to a commercially available NJOY Ace with a commercially available pods, and the subject's commercially available usual brand (UB) of combustible cigarette. Subjective effects will also be assessed to gain an understanding of nicotine withdrawal and dependence, satisfying and reinforcing effects.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/10/2024, WCG Institutional Review Board (212 Carnegie Center, Suite 301, Princeton, 08540, United States of America; +1 855 818 2289; clientcare@wcgclinical.com), ref: 20243974

Study design
Interventional randomized controlled crossover single center study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Pharmaceutical testing facility, Telephone

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Nicotine exposure

Interventions
Randomization:
The study will enroll 30 adult smokers in each study part (A and B), smokers of non-menthol cigarettes in Part A and smokers of menthol cigarettes in Part B, to ensure 28 subjects complete a controlled and an ad libitum session with each study product, in each study part. Additional subjects may be enrolled to replace subjects who withdraw prematurely from the study or do not complete required PK testing. Each part of the study will have 4 randomization sequences (ABCD, BCDA, DABC, or CDAB).
Subjects will be screened for participation up to 28 days before pre-randomization assessments on Check-in (Day -1). On Screening Day 2, following successful completion of all clinical laboratory testing screening procedures, subjects will be trained on the correct use of the JUUL2 devices and pods by way of a training video and be instructed on the use of NJOY Ace products per the manufacturer's directions. Trained subjects will have the opportunity to try, ad libitum, a JUUL2 Device and Pod with 3% and 5% nicotine and NJOY Ace product with 5% nicotine; subjects will be provided Tobacco or Menthol flavors based on the study Part into which they are enrolled. For study products the subjects wish to try, one pod of each will be dispensed;

requested products with 5% nicotine will be provided first. Subjects who do not tolerate or object to further using a product will be considered to have failed screening and should not be administered other study products.
Subjects also will be assessed on their ability to properly complete the controlled puffing sequence, and draw down the JUUL2 pod by 20-60 mg, using one JUUL2 Device and a 5% nicotine Pod.
Once a subject fulfils the enrollment criteria including specific requirements on Day -1, they are eligible to be randomized into the study.
On study Days 1 through 4, subjects will first perform a controlled use session, followed by a 5-minute ad libitum use session, separated by at least 4 hours of nicotine product abstention. Blood will be drawn at set times to assess plasma nicotine levels and PK, and subjects will also complete subjective measures questionnaires during the controlled as well as the ad libitum sessions.

Part A
1. JUUL2 Device with Virginia Tobacco flavored e-liquid with 3% nicotine concentration JUUL2 pod
2. JUUL2 Device with Virginia Tobacco flavored e-liquid with 5% nicotine concentration JUUL2 pod
3. NJOY Ace Device with Classic Tobacco flavored e-liquid with 5% nicotine concentration Ace pod
4. Subject’s usual brand (UB) combustible non-menthol cigarette

Part B
1. JUUL2 Device with Fresh Menthol flavored e-liquid with 3% nicotine concentration JUUL2 pod
2. JUUL2 Device with Fresh Menthol flavored e-liquid with 5% nicotine concentration JUUL2 pod
3. NJOY Ace Device with Menthol flavored e-liquid with 5% nicotine concentration Ace pod
4. Subject’s usual brand (UB) combustible menthol cigarette

Methodology:
Each day the subject will be provided with the assigned product for that day for their controlled and ad-lib product use sessions. Blood samples will be taken throughout the product use sessions and subjective assessment questionnaires will be taken throughout each day.

Dosage: Dosage is not a term used for tobacco studies, as this is not a medicinal trial. However, the JUUL2 Product has 3& or 5% nicotine and the nicotine in the subjects' usual brand cigarettes will vary based on the brand, the NJOY ACE product has 5.0% nicotine. Changes in JUUL2 Product pod weight will recorded, as well as the number of cigarettes smoked and the amount of JUUL2 and NJOY product used (number of pods).

Frequency:
During the study product use sessions on each of the four study days, subjects will use a single study product according to the randomized product use sequence. No other use of tobacco or nicotine-containing products will be allowed before or during the testing sessions. The start and stop time of each product use session will be documented. On each study day, subjects will complete the controlled use session, followed by at least a 4-hour nicotine abstention period, and then the 5- 5-minute ad libitum use session using the same assigned study product.
For controlled puff sessions, blood samples for nicotine analysis will be collected approximately 5 minutes prior to initiation of the first product use (i.e., -5 minutes ± 2, the baseline sample) and approximately 1.5, 3, 5, 6, 7, 8, 10, 15, 30, 60, and 120 minutes after initiation of study product use.
For ad libitum sessions, blood samples for nicotine analysis will be collected approximately 5

minutes prior to initiation of the ad libitum session (i.e., -5 minutes ± 2, the baseline sample) and approximately 1.5, 3, 5, 6, 7, 8, 10, 15, 30, 60, and 120 minutes after initiation of the ad libitum session.
The mPES, Product-Liking, and Future Intent to Use the Product Questionnaires will be completed at approximately 30 minutes post-start of each product use session (controlled and ad libitum use session, after collecting the 30-minute blood sample during both the controlled and ad libitum product use sessions).
The Urge to Smoke a Cigarette Questionnaire will be administered 10 minutes prior to the first puff, and at 5, 10, 15, 30, and 45 minutes relative to the first puff during each puffing session (controlled and ad libitum use session, after collecting any coincident blood sample during both the controlled and ad libitum product use sessions).
All pods (without caps) will be weighed before and after both the controlled and ad libitum sessions for each subject. The change in weight between these two measurements will be recorded.

Follow up:
Study site personnel will perform a follow-up telephone call at 7±2 days post study Day 5 (or early termination). During this call, the Principal Investigator (PI) or designee, will obtain information on any new or changes to Adverse Events (AEs) and new or changes to concomitant medications associated with an AE since the last site visit. If there are no AEs that require further attention, the subject's participation in the study will be complete

Intervention Type
Device

Pharmaceutical study type(s)
Pharmacokinetic

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
JUUL2 ENDS Devices with JUUL2 pods, Virginia Tobacco or Fresh Menthol flavors, at 3% and 5% nicotine

Primary outcome measure
Maximum baseline concentration (Cmax-BL) and the area under the curve from 0 to 120 minutes baseline (AUC0-120-BL) of the JUUL2 ENDS Devices with JUUL2 pods (Virginia Tobacco or Fresh Menthol flavors, 3% and 5% nicotine) compared to the subject's usual brand (UB) of combustible cigarettes, under controlled puffing conditions (10 puffs of 3 seconds each, spaced 30 seconds apart) measured using blood samples drawn at approximately -5, 1.5, 3, 5, 6, 7, 8, 10, 15, 30, 60, and 120 minutes after first product use

Secondary outcome measures
1. Nicotine pharmacokinetics (PK) while using the JUUL2 ENDS Devices with JUUL2 pods, Virginia Tobacco or Fresh Menthol flavors, 3% and 5% nicotine, as compared to the subject's UB of combustible cigarettes during controlled and 5-minute ad libitum puffing conditions measured using blood samples drawn at approximately -5, 1.5, 3, 5, 6, 7, 8, 10, 15, 30, 60, and 120 minutes after first product use
2. Nicotine PK while using a commercially available ENDS Device with pod during controlled and 5-minute ad libitum puffing conditions measured using blood samples drawn at approximately

-5, 1.5, 3, 5, 6, 7, 8, 10, 15, 30, 60, and 120 minutes after first product use
3. The following subjective assessments will be assessed with the use of the JUUL2 ENDS Devices with JUUL2 pods, Virginia Tobacco or Fresh Menthol flavors, 3% and 5% nicotine, a commercially available ENDS Device with a pod, and the subject's UB of combustible cigarettes (the responses will be summarized in descriptive statistics tables):
3.1. Subjective responses to the use of study products measured using the Modified Product Evaluation Scale (mPES) at approximately 30 minutes post-start of each product use session (controlled and ad libitum use session, after collecting the 30-minute blood sample during both the controlled and ad libitum product use sessions)
3.2. Subjective responses to the liking of the products measured using the Product-Liking Questionnaire at approximately 30 minutes post-start of each product use session (controlled and ad libitum use session, after collecting the 30-minute blood sample during both the controlled and ad libitum product use sessions)
3.3. Subjective responses to the urge to smoke measured using the Urge to Smoke a Cigarette Questionnaire approximately 10 minutes prior to first puff, and at 5, 10, 15, 30, and 45 minutes relative to the first puff during each puffing session (controlled and ad libitum use session, after collecting any coincident blood sample during both the controlled and ad libitum product use sessions)
3.4. Subjective responses to the future intention to use the product measured using the Future Intent to Use the Product Questionnaire approximately 30 minutes post-start of each product use session (controlled and ad libitum use session, after collecting the 30-minute blood sample during both the controlled and ad libitum product use sessions).
4. Product usage measured by changes in pod weights while using ENDS study products before and after both the controlled and ad libitum sessions for each subject

The exploratory outcome measure is:
5. Puffing topography measured using data collected by the device while using JUUL2 test products

Overall study start date
07/10/2024

Completion date
01/05/2025

Eligibility

Key inclusion criteria
Subjects must meet all of the following inclusion criteria to be eligible for participation in the study:
1. Provides voluntary consent to participate in this study documented on the signed ICF(s).
2. Adult, male or female smoker, 22 to 65 years of age, inclusive, verified by government-issued ID, at the Screening visit.
3. Has been a smoker ≥ 12 months prior to Screening.
4. Currently smokes an average of ≥10 manufactured combustible cigarettes per day (CPD), as self-reported at Screening.
5. Has past 30-day history of some day or everyday ENDS use.
6. Has a positive urine cotinine (≥200 ng/mL) at the Screening visit and Check-in/Day -1.
7. Has an exhaled carbon monoxide (eCO) ≥10 ppm at the Screening visit.
8. Completes the screening process within 28 days prior to study Day -1.
9. Is willing to comply with the requirements of the study, including a willingness to use the

study products during the study and to stop smoking during the required abstention periods in the study.
10. A female subject of childbearing potential must have been using one of the following forms of contraception, and agree to continue using it through the completion of the study:
10.1. Hormonal (e.g., oral, vaginal ring, transdermal patch, implant, or injection) consistently for at least 3 months prior to study Day 1;
10.2. Double-barrier method (e.g., condom with spermicide, diaphragm with spermicide) from Day 1;
10.3.3 Intrauterine device for at least 3 months prior to study Day 1;
10.4. Abstinence beginning at least 6 months prior to Day 1;
10.5. a partner who has been vasectomized for at least 6 months prior to Day 1.
11. A female subject of non-childbearing potential must be postmenopausal with amenorrhea for at least 1 year prior to study Day 1 and follicle-stimulating hormone (FSH) levels consistent with postmenopausal status or have undergone one of the following sterilization procedures at least 6 months prior to study Day 1:
11.1. Hysteroscopic sterilization;
11.2. Bilateral tubal ligation, occlusion, or bilateral salpingectomy;
11.3. Hysterectomy;
11.4. Bilateral oophorectomy

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
22 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Total final enrolment
56

Key exclusion criteria
1. Has a history or presence of clinically significant gastrointestinal, renal, hepatic, neurologic, hematologic, endocrine, laryngeal, oncologic, urologic, pulmonary (asthma, chronic obstructive pulmonary disease), immunologic, psychiatric, cardiovascular disease (hypertension, heart failure, chronic coronary syndrome, post-myocardial infarction status), diabetes mellitus, or any other condition that, in the opinion of the Investigator, would jeopardize the safety of the subject or impact the validity of the study results.
2. Has a clinically significant abnormal finding on the physical examination, medical history, vital signs, electrocardiogram (ECG), in the opinion of an Investigator and any abnormal findings in clinical laboratory results at the Screening visit.

3. Has had an acute illness (e.g., upper respiratory infection, viral infection) requiring treatment within 28 days prior to study Day -1.
4. Has a positive test result to HIV Ag/Ab combo, HBsAg or HCVAb at Screening.
5. Has a fever (>100.4°F [38oC]) at the first Screening visit or at Check-in/Day -1.
6. Has a body mass index (BMI) ≥ 40 kg/m2 or < 18 kg/m2 at Screening.
7. Has a positive urine test result for alcohol or drugs of abuse at the Screening visit or at Check-in/Day -1. If positive for THC at check-in (Day -1), a cannabis intoxication evaluation will be performed and inclusion will be at the discretion of an investigator. If a positive urine drug test is observed, and it is believed that the positive urine test is due to prescription drugs, an investigator should obtain documentation that;
7.1. Confirms the subject's use of the prescribed medication, and
7.2. The prescribed medication will cause a false positive drug test.
8. Has a current history of routinely smoking marijuana. A current history of marijuana edible use is allowed at an investigator's discretion.
9. Has a systolic blood pressure (SBP) <90 mmHg or >150 mmHg, diastolic blood pressure (DBP) <40 mmHg or >95 mmHg, or HR <40 beats per minute (bpm) or >99 bpm at Screening.
10. Has experienced an allergic reaction following previous e-cigarette use or with exposure to any primary components of the e-liquids (nicotine, flavor, benzoic acid, propylene glycol and glycerol).
11. Has participated in a previous clinical study for an investigational drug, device, biologic, or tobacco product within 30 days prior to Screening.
12. Has donated blood or blood products >500 mL, had significant blood loss, or received whole blood or a blood product transfusion within 56 days or has donated plasma within 7 days prior to Screening.
13. If female, the subject is pregnant, has a positive pregnancy test at the Screening visit or at Check-in/Day -1, is lactating, breastfeeding, or intends to become pregnant during the time period from Screening through the follow-up call.
14. Has used medications known to interact with cytochrome P450 (CYP) 2A6 (including, but not limited to, amiodarone, amlodipine, amobarbital, buprenorphine, clofibrate, clotrimazole, desipramine, disulfiram, entacapone, fenofibrate, isoniazid, ketoconazole, letrozole, methimazole, methoxsalen, metyrapone, miconazole, modafinil, orphenadrine, pentobarbital, phenobarbital, pilocarpine, primidone, propoxyphene, quinidine, rifampicin, rifampin, secobarbital, selegiline, sulconazole, tioconazole, tranylcypromine) within 14 days or 5 half-lives of the drug, whichever is longer, prior to study Day 1.
15. Has used medications reported to interact with nicotine, including theophylline, ropinirole, and clozapine, within 14 days or 5 half-lives of the drug, whichever is longer, prior to study Day 1.
16. Has used any prescription smoking cessation treatments, including, but not limited to, varenicline (Chantix®) or bupropion (Zyban®) within 30 days prior to study Day 1.
17. Requires concomitant treatment with prescription or non-prescription products that contain pseudoephedrine (e.g., nasal/sinus decongestants).
18. Negative response (i.e., unwilling to use or unable to tolerate [e.g., experiences adverse events (AEs) during the product familiarization that will prevent the subjects from continuing to use the JUUL product as judged by an investigator]) to any of the JUUL products at the Screening visit.
19. Is a self-reported puffer (i.e., adult smokers who draw smoke from the cigarette and/or e-cigarette into the mouth and throat but do not inhale).
20. Are planning to quit smoking during the study or postponing a quit attempt in order to participate in the study
21. Unable to perform the controlled puffing sequence (CPS) and draw down the JUUL2 pod weight by 20-60 mg after 3 attempts at the Screening visit.
22. Unwilling or unable to comply with study-related procedures including but not limited to; schedule of assessment, PK draws and placement of catheter.

23. Is or has a first-degree relative (i.e., parent, sibling, child) who is a current employee of the study site or shareholder, or is a member of the board of directors of JUUL Labs, Inc.
24. Is or has a first-degree relative (i.e., parent, sibling, child) who is a litigant in a lawsuit against an ENDS manufacturer.
25. Has previously taken part in, has been excluded or withdrawn from, or has completed this study.
26. Has previously been diagnosed with any form of cancer, except for basal cell or squamous epithelial carcinomas of the skin that have been resected at least 1 year prior to Screening.
27. In the opinion of an Investigator, the subject should not participate in this study.

Date of first enrolment
15/10/2024

Date of final enrolment
20/12/2024

Locations

Countries of recruitment
United States of America

Study participating centre
Dr. Vince Clinical Research
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Sponsor information

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Funder Name
JUUL Labs Inc

Results and Publications

Publication and dissemination plan
All unpublished information provided by the Sponsor shall not be published or disclosed to a third party without the prior written consent of the Sponsor. The data generated by this study are considered confidential information and the property of the Sponsor. This confidential information may be published only in collaboration with participating personnel from the Sponsor or upon the Sponsor's written consent to publish the information. Data arising from the study will be considered for dissemination at scientific conferences and in the peer-reviewed literature after completion of the study. No other documents will be available.

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the dataset may contain commercially-sensitive information.

IPD sharing plan summary
Not expected to be made available