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A first-in-human study to investigate safety, tolerability, and pharmacokinetics of single and multiple ascending doses of JZP505 in healthy adult participants

Submission date
26/06/2024

Recruitment status
No longer recruiting

Registration date
27/06/2024

Overall study status
Completed

Last Edited
24/07/2026

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
This is a clinical study of an investigational drug called JZP505. An investigational drug has not yet been approved for doctors to prescribe. This is a "first-in-human" study, meaning it is the first time JZP505 has been given to people, although it has been tested in animals.

The main goals of this study are to learn more about:
-The safety of the study drug and any possible side effects.
-How the body takes in and gets rid of the study drug (this is called pharmacokinetics).
-Whether taking the study drug with food changes how it works.
-How the study drug affects the brain, including any changes to mood, sleepiness, or brain wave activity (which is measured with a test called an EEG).

Who can participate?
The study is looking for about 96 healthy volunteers. Participants can be male or female and must be between 18 and 55 years old. To be in the study, participants must be in good health and meet certain guidelines, such as having a healthy weight for their height.

For safety reasons, some people cannot join the study. This includes people who have had thoughts of self-harm, serious allergies, or certain kidney or heart problems. There are also rules about lifestyle, such as not using cannabis or tobacco products for 3 months before the study.

What does the study involve?
This is a randomly allocated, double-blind, placebo-controlled study. Randomization means that participants are chosen by chance (like flipping a coin) to get either JZP505 or a placebo. A placebo is a substance that looks like the study drug but contains no active ingredient. Double-blind means that neither the participant nor the study doctor will know who is getting the real drug and who is getting the placebo.

The study has two parts:
Part A (Single Dose): Participants will get one dose of the study drug or placebo. This part requires staying at the study clinic for 5 days.
Part B (Multiple Doses): Participants will get a dose of the study drug or placebo every day for 7 days. This part requires staying at the clinic for 11 days.

In total, being in the study will last between 5 and 8 weeks. While at the clinic, participants will have many health checks, including physical exams, blood and urine tests, and tests to check their heart (ECG) and brain (EEG) activity.

What are the possible benefits and risks of participating?
Benefits: Since this study is for healthy people, there are no direct medical benefits to joining. However, the information we learn might help develop a new medicine for others in the future.
Risks: Because this is the first time JZP505 is being given to people, there could be side effects that we don't know about yet. Based on what we know so far, possible risks could include:

-Injury to the liver. This will be monitored with regular blood tests.
-Feeling drowsy, sleepy, or tired
-Thoughts of self-harm. This will be monitored by asking questions about mood
-A serious allergic reaction

The study tests themselves may have risks, like bruising from a blood draw or skin irritation from the test sensors.

Where is the study run from?
The research clinic is Labcorp Clinical Research Unit, formerly Fortrea, Leeds, England.

When is the study starting and how long is it expected to run for?
April 2023 to January 2024.

Who is funding the study?
GW Research Ltd / JAZZ Pharmaceuticals Research UK Ltd.

Who is the main contact?
Clinical Trial Disclosure and Transparency, ClinicalTrialDisclosure@jazzpharma.com

Contact information

Type(s)
Public, Scientific

Contact name
Dr - Clinical Trial Disclosure and Transparency

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Additional identifiers

Integrated Research Application System (IRAS)
1006698

Study information

Scientific Title
A phase 1, first-in-human, randomized, double-blind, placebo-controlled, safety, tolerability, and pharmacokinetic study with single and multiple ascending doses and food effect of JZP505 in healthy adult participants

Study objectives
1. Safety
2.Tolerability
3. Pharmacokinetics

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 19/01/2023, London-Brent Research Ethic Committee (80 London Road, Skipton House, London, SE1 6LH, United Kingdom; +44 (0)20 3080 6456; brent_rec@hra.nhs.uk), ref: 22/LO/0850

2. Approved 07/03/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6456; clintrialhelpline@mhra.gov.uk), ref: CTA 36772/0031/001-0001

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking

Blinded (masking used)

Control
Placebo

Assignment
Sequential cohort, parallel design

Purpose
Treatment

Study type(s)
Safety

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
Experimental Drug: JZP505
Control Drug: Placebo

A single-site, randomized (by computer), double-blind, single-ascending dose (SAD) and multiple-ascending dose (MAD) study of JZP505 will be conducted in 2 parts (Part A: SAD + food effect; Part B: MAD)

Dosing:
SAD: Single oral doses of JZP505 or placebo (150mg-2400mg)
Food Effect: Two single oral doses of JZP505 or placebo in fasted and fed states in Cohort A2 (300mg)
MAD: Once or twice daily oral dosing of JZP505 or placebo for 7 days (200mg-1000mg)

Cohorts:
SAD: 7 (Cohorts A1 to A7)
SAD Food Effect: Cohort A2 (fed and fasted)
MAD: 5 (Cohorts B1 to B5)

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
JZP505

Primary outcome(s)
1. Part A: Incidence and severity of treatment-emergent adverse events (TEAEs) measured using the number of participants at Day 1 up to 9 months
2. Part A: Change in clinical laboratory test parameters measured using IU/L (International Units per Litre) at Day 2: 24 hours postdose; Day 4: 72 hours postdose
3. Part A: Changes in 12-lead electrocardiogram (ECG) parameters measured using milliseconds

(ms) at Predose (Day 1) and 1, 2, 4, 8, 12, 24, and 72 hours postdose
4. Part A: Changes in vital sign measurements-supine blood pressure measured using mmHg at Day 1: predose and 1, 2, 4, 8 hours postdose; Day 2: 24 hours postdose; Day 3: 48 hours postdose; Day 4: 72 hours postdose
5. Part A: Changes in vital sign measurements-pulse rate measured using beats/min at Day 1: predose and 1, 2, 4, 8 hours postdose; Day 2: 24 hours postdose; Day 3: 48 hours postdose; Day 4: 72 hours postdose
6. Part A: Changes in vital sign measurements-respiratory rate measured using breaths/min at Day 1: predose and 1, 2, 4, 8 hours postdose; Day 2: 24 hours postdose; Day 3: 48 hours postdose; Day 4: 72 hours postdose
7. Part A: Changes in vital sign measurements-oral temperature measured using celcius (°C) at Day 1: predose and 1, 2, 4, 8 hours postdose; Day 2: 24 hours postdose; Day 3: 48 hours postdose; Day 4: 72 hours postdose
8. Part A: Changes in Columbia Suicide Severity Rating Scale (C-SSRS) Assessment measured using C-SSRS at Baseline and final visit
9. Part A: Maximum observed plasma concentration (Cmax) measured using ng/mL at Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, and 72 hours postdose
10. Part A: Area under the plasma concentration-time curve from time zero to the time of the final quantifiable concentration (AUCt) measured using h*ng/mL at Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, and 72 hours postdose
11. Part A: Area under the plasma concentration-time curve from time zero extrapolated to infinity (AUC∞) measured using h*ng/mL at Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, and 72 hours postdose
12. Part A: Time of maximum observed plasma concentration (Tmax) measured using hours at Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, and 72 hours postdose
13. Part A: Time prior to the first quantifiable plasma concentration (Tlag) measured using hours at Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, and 72 hours postdose
14. Part A: Terminal elimination half-life (t½) measured using hours at Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, and 72 hours postdose
15. Part A: Apparent volume of distribution after oral dose (Vz/F) measured using L at Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, and 72 hours postdose
16. Part A: Apparent oral clearance (CL/F) measured using L/h at Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, and 72 hours postdose
17. Part B: Incidence and severity of TEAEs measured using Number of Participants at Day 1 up to 9 months
18. Part B: Change in clinical laboratory test parameters measured using IU/L at Days 3 and 6: predose; Day 9: 48 hours after last dose of study intervention; Day 19 to 21
19. Part B: Changes in 12-lead ECG parameters measured using ms at Days 1, 3, and 6: predose and 4 hours postdose, and at matched time points on Days 8 and 10
20. Part B: Changes in vital sign measurements-supine blood pressure measured using mmHg at Day 1: predose and 1, 2, 4, and 8 hours postdose; Days 2 to 6: predose; Day 7: predose and 4 hours postdose; Days 8 (24 hours), 9 (48 hours), and 10 (72 hours) post Day 7 dose
21. Part B: Changes in vital sign measurements -pulse rate measured using beats/min at Day 1: predose and 1, 2, 4, and 8 hours postdose; Days 2 to 6: predose; Day 7: predose and 4 hours postdose; Days 8 (24 hours), 9 (48 hours), and 10 (72 hours) post Day 7 dose
22. Part B: Changes in vital sign measurements-respiratory rate measured using breaths/min at Day 1: predose and 1, 2, 4, and 8 hours postdose; Days 2 to 6: predose; Day 7: predose and 4 hours postdose; Days 8 (24 hours), 9 (48 hours), and 10 (72 hours) post Day 7 dose
23. Part B: Changes in vital sign measurements-oral temperature measured using celcius (°C) at Day 1: predose and 1, 2, 4, and 8 hours postdose; Days 2 to 6: predose; Day 7: predose and 4 hours postdose; Days 8 (24 hours), 9 (48 hours), and 10 (72 hours) post Day 7 dose
24. Part B: Changes in Columbia Suicide Severity Rating Scale (C-SSRS) Assessment measured

using C-SSRS at Baseline and final visit
25. Part B: Cmax measured using ng/mL at Day 1: Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16 hours postdose; Day 2 to 6: Predose; Day 7: Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16 hours postdose; Day 8: 24 hours postdose; Day 9: 48 hours postdose; Day 10: 72 hours postdose
26. Part B: AUCt measured using h*ng/mL at Day 1: Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16 hours postdose; Day 2 to 6: Predose; Day 7: Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16 hours postdose; Day 8: 24 hours postdose; Day 9: 48 hours postdose; Day 10: 72 hours postdose
27. Part B: Area under the concentration-time curve over the dosing interval (AUC(0-τ)) measured using h*ng/mL at Day 1 and Day 7
28. Part B: Tmax measured using hours at Day 1: Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16 hours postdose; Day 2 to 6: Predose; Day 7: Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16 hours postdose; Day 8: 24 hours postdose; Day 9: 48 hours postdose; Day 10: 72 hours postdose
29. Part B: Tlag measured using hours at Day 1: Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16 hours postdose; Day 2 to 6: Predose; Day 7: Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16 hours postdose; Day 8: 24 hours postdose; Day 9: 48 hours postdose; Day 10: 72 hours postdose
30. Part B: t½ measured using hours at Day 1: Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16 hours postdose; Day 2 to 6: Predose; Day 7: Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16 hours postdose; Day 8: 24 hours postdose; Day 9: 48 hours postdose; Day 10: 72 hours postdose
31. Part B: Accumulation ratio (Rac) based on AUC(0-τ) of Day 7 versus Day 1 measured using Rac, AUC at Day 1 and Day 7
32. Part B: Rac based on Cmax of Day 7 versus Day 1 measured using Rac, Cmax at Day 1 and Day 7
33. Part B: Effective t½ (t½, eff) measured using hours at Day 1: Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16 hours postdose; Day 2 to 6: Predose; Day 7: Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 16 hours postdose; Day 8: 24 hours postdose; Day 9: 48 hours postdose; Day 10: 72 hours postdose

Key secondary outcome(s)

1. Part A: Dose proportionality of JZP505 for Cmax measured using ng/mL at Day 1
2. Part A: Dose proportionality of JZP505 for AUCt measured using h*ng/mL at Day 1
3. Part A: Dose proportionality of JZP505 for AUC∞ measured using h*ng/mL at Day 1
4. Part A: Cumulative amount of unchanged drug excreted into the urine (Ae0-t) measured using mg at Day 1: Predose, 0-6, 6-12, 12-24, 24-48, and 48-72 hours postdose
5. Part A: The amount of drug excreted in urine as a percentage of administered dose (Fe %) measured using % at Day 1: Predose, 0-6, 6-12, 12-24, 24-48, and 48-72 hours postdose
6. Part A: Renal clearance (CLR) measured using L/h at Day 1: Predose, 0-6, 6-12, 12-24, 24-48, and 48-72 hours postdose
7. Part A: Change from Baseline in central nervous system (CNS)-related effects as determined by Bond-Lader VAS measured using mm at Day 1: predose and 2, 4, 8, and 12 hours postdose; Day 2: 24 hours postdose; Day 4: 72 hours postdose
8. Part A: Fed and fasted state Cmax following a single dose of JZP505 measured using ng/mL at Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, and 72 hours postdose
9. Part A: Fed and fasted state AUCt following a single dose of JZP505 measured using h*ng/mL at Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, and 72 hours postdose
10. Part A: Fed and fasted state AUC∞ following a single dose of JZP505 measured using h*ng /mL at Predose and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, and 72 hours postdose

11. Part A: Incidence and severity of TEAEs in fed and fasted state measured using number of participants at Day 1 up to 9 months
12. Part A: Change in clinical laboratory test parameters in fed and fasted State measured using IU/L at Day 2: 24 hours postdose; Day 4: 72 hours postdose
13. Part A: Changes in 12-lead ECG parameters in fed and fasted State measured using ms at Predose (Day 1) and 1, 2, 4, 8, 12, 24, and 72 hours postdose
14. Part A: Changes in vital sign measurements-supine blood pressure in fed and fasted state measured using mmHG at Day 1: predose and 1, 2, 4, 8 hours postdose; Day 2: 24 hours postdose; Day 3: 48 hours postdose; Day 4: 72 hours postdose
15. Part A: Changes in vital sign measurements-pulse rate in fed and fasted state measured using beats/min at Day 1: predose and 1, 2, 4, 8 hours postdose; Day 2: 24 hours postdose; Day 3: 48 hours postdose; Day 4: 72 hours postdose
16. Part A: Changes in vital sign measurements-respiratory rate in fed and fasted state measured using breaths /min at Day 1: predose and 1, 2, 4, 8 hours postdose; Day 2: 24 hours postdose; Day 3: 48 hours postdose; Day 4: 72 hours postdose
17. Part A: Changes in vital sign measurements-oral temperature in fed and fasted state measured using celcius (°C) at Day 1: predose and 1, 2, 4, 8 hours postdose; Day 2: 24 hours postdose; Day 3: 48 hours postdose; Day 4: 72 hours postdose
18. Part A: Changes in Columbia Suicide Severity Rating Scale (C-SSRS) Assessment in fed and fasted state measured using C-SSRS at Baseline and final visit
19. Part B: Dose proportionality of JZP505 for Cmax measured using ng/mL at Day 1 and Day 7
20. Part B: Dose proportionality of JZP505 for AUC(0- τ) measured using h*ng/mL at Day 1 and Day 7
21. Part B: Cumulative amount of unchanged drug excreted into the urine across the dosing interval (Aetau) measured using h*ng/mL at Day 1: Predose, 0-6, 6-12, 12-24 hours postdose; Day 7: Predose, 0-6, 6-12, 12-24 hours postdose
22. Part B: The amount of drug excreted in urine as a percentage of administered dose (Fe %) measured using % at Day 1: Predose, 0-6, 6-12, 12-24 hours postdose; Day 7: Predose, 0-6, 6-12, 12-24 hours postdose
23. Part B: Renal clearance (CLR) measured using L/h at Day 1: Predose, 0-6, 6-12, 12-24 hours postdose; Day 7: Predose, 0-6, 6-12, 12-24 hours postdose
24. Part B: Change from Baseline in CNS-related effects as determined by Bond-Lader VAS measured using mm at Days 1, 5, and 7: predose and 2, 4, 8, and 12 hours postdose (pre- PM dose for BID-dosed cohorts)

Completion date
12/01/2024

Eligibility

Key inclusion criteria
Age
1. Is 18 to 55 years of age inclusive at the time of signing the informed consent

Type of Participant and Disease Characteristics
2. Are overtly healthy as determined by medical evaluation, including medical history, physical examination, laboratory tests, and cardiac monitoring

Weight
3. Has a minimum body weight of 50 kg and a BMI within the range 18.5 to 32 kg/m2, inclusive
4. Is male or female:

4.1. Male participants are eligible to participate if they agree to the following during the study intervention period and for at least 90 days after the last dose of study intervention:
4.1.1. Refrain from donating sperm.
PLUS either of the following:
4.1.2. Be abstinent from heterosexual intercourse as their preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent
OR
4.1.3. Use contraception/barrier as follows:
4.1.3.1. Use a male condom with female partner use of an additional highly effective contraceptive method with a failure rate of < 1% per year as described in Contraceptive and Barrier Requirements when having sexual intercourse with a WOCBP who is not currently pregnant
4.1.3.2. Agree to use a male condom when engaging in any activity that allows for passage of ejaculate to another person
4.2. Female participants are eligible to participate if:
4.2.1. She is a WONCBP, as defined in Contraceptive and Barrier Guidance

Informed Consent
5. Is capable of giving signed informed consent, which includes compliance with the requirements and restrictions listed in the ICF and in this protocol

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
55

Key exclusion criteria
Medical Conditions
1. Any history of suicidal behavior or any suicidal ideation, as indicated by a positive response to Item 4 or Item 5 on the C-SSRS, or past or current history of self-harm thoughts or actions as identified on C-SSRS at screening
2. Presence or history of significant hypersensitivity, intolerance, or allergy to any drug compound, food, or other substance, as determined by the investigator (or designee); any known or suspected hypersensitivity to cannabinoids, or any of the excipients of JZP505. Hay fever is allowed unless it is active

3. Presence of congenital nonhemolytic hyperbilirubinemia (eg, Gilbert's syndrome) at either screening or admission on Day –1, as assessed by the investigator (or designee)
4. History of stomach or intestinal surgery or resection that would potentially alter absorption and/or excretion of orally administered drugs
5. History of drug abuse within 2 years of screening or current habituation to any medications or illegal drugs
6. Any history of fits/seizures (apart from childhood febrile convulsions before the age of 6 years). Known or suspected history or family history of schizophrenia or other psychotic illness; history of severe personality disorder or other significant psychiatric disorder
7. Poor peripheral venous access
8. Clinically significant renal disease, nephrectomy, renal transplant or estimated glomerular filtration rate of < 60 mL/min/1.73 m2 at screening based on the MDRD equation

Prior/Concomitant Therapy
9. Use or intend to use any prescription medications or nonprescription drugs within 14 days or 5 half-lives, whichever is longer, prior to Check-in on Day –1

Prior/Concurrent Clinical Study Experience
10. Participation in a clinical trial involving administration of a study intervention (new chemical entity) in the past 3 months.

Diagnostic Assessments
11. Positive serology panel (including hepatitis B surface antigen and hepatitis C virus antibody) and/or positive human immunodeficiency virus antibody/p24 antigen screens
12. Positive alcohol breath test result, cotinine test, or positive urine drug screen (may be confirmed by repeat) at screening or Check-in on Day –1
13. Participant has impaired hepatic function at screening or Check-in on Day –1 (confirmed by repeat assessment), defined as any of the following:
13.1. Serum ALT or AST > 1.0 × ULN
13.2. TBL > ULN
13.3. INR > ULN
13.4. Serum creatinine > 1 × ULN
14. Hemoglobin level < 13.5 g/dL (male participants) or < 12.5 g/dL (female participants) at screening or Check-in on Day 1
15. Absolute neutrophil count < 2 × 109/dL at screening or Check-in on Day 1
16. Participants with a supine systolic blood pressure at screening of < 90 mmHg (or > 140 mmHg) or a diastolic blood pressure of < 50 mmHg (or > 90 mmHg), confirmed by repeat readings
17. Participants with an orthostatic decrease in systolic blood pressure > 20 mmHg, or a decrease in diastolic blood pressure >10 mmHg upon standing
18. Clinically significant ECG abnormality at screening (confirmed by repeat within 2 hours), including, but not limited to:
18.1. PR interval > 220 msec
18.2. QRS duration > 120 msec
18.3. Complete left or right bundle branch block, second- or third-degree heart block
18.4. QTcF > 450 msec for male participants or > 470 msec for female participants; the ECG may be repeated up to 2 times at the investigator's discretion for confirmation (with 2 of 3 ECGs being below the threshold)
18.5. History of additional risk factors for torsade de pointes (eg, heart failure, clinically significant hypokalemia [< 2.5 mmol/L])
18.6. Family history of long QT syndrome
18.7. Evidence of prior myocardial infarction

18.8. Clinically significant ST segment or T wave abnormalities or any other abnormality that is clinically significant in the investigator’s opinion or precludes accurate interpretation and calculations of cardiac intervals (eg, QRS)

Other Exclusions
19. Receipt of blood products within 2 months prior to Check-in on Day –1. Donation or loss of blood (≥ 450 mL) from 3 months prior to screening, plasma from 2 weeks prior to screening, or platelets from 6 weeks prior to screening
20. Participant has been vaccinated within 28 days prior to admission on Day –1 and/or plans to obtain a vaccination during the trial
21. Participant is currently using or has used cannabis (recreational or medicinal), synthetic CBD-based medications within the 3 months prior to screening, or cannabinoid-based medications (eg, dronabinol and nabilone) within 30 days of trial entry or is unwilling to abstain for the duration of the trial
22. Alcohol consumption of > 21 units per week (males) or > 14 units per week (females). One unit of alcohol equals ½ pint (285 mL) of beer or lager, 1 glass (125 mL) of wine, or ⅙ gill (25 mL) of spirits
23. Use of tobacco- or nicotine-containing products within 3 months prior to Check-in on Day –1

Date of first enrolment
18/04/2023

Date of final enrolment
12/01/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Fortrea Clinical Research Unit Limited
Draper's Yard Marshall Street
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England
LS11 9EH

Sponsor information

Organisation
JAZZ Pharmaceuticals Research UK Ltd

Funder(s)

Funder type
Not defined

Funder Name
JAZZ Pharmaceuticals Research UK Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available