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A phase 1 open-label study to assess the safety and PK of novel CBD soft-gel capsule

Submission date	Recruitment status	[X] Prospectively registered
05/02/2025	Not yet recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/08/2025	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/08/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to test a new version of cannabidiol (CBD) to understand how the body processes it and to ensure it is safe for use in healthy volunteers. CBD is a natural compound found in the cannabis plant that has shown promise in treating various medical and mental health conditions. Currently, an FDA-approved CBD drug called Epidyolex is used to treat epilepsy. However, many CBD products don't absorb well in the body when taken by mouth, making them less effective and requiring higher doses.
NW PharmaTech has developed a new CBD formulation designed to improve how the body absorbs and processes it. This study will compare the pharmacokinetics, safety, and tolerability of two different doses (600 and 900 mg) of the new formulation (NW300EMCBD) to Epidyolex. Across three separate treatment periods, participants will receive the following dose regimens in a randomised order across 3 treatment periods: (A) 600 mg NW300EMCBD administered orally following a HFHC meal; (B) 900 mg NW300EMCBD administered orally following a HFHC meal; (C) 25 mg/kg Epidyolex solution administered orally as 2 x 12.5 mg/kg doses separated by 12 hours, each following a HFHC meal.
Researchers will examine how the body absorbs, distributes, and eliminates each formulation. The goal is to find the best dose and formulation that works effectively while minimizing side effects.

Who can participate?
Healthy volunteers aged between 18 and 55 years.

What does the study involve?
All participants will receive the following dose regimens in a randomised order across 3 treatment periods:
• Regimen A: 600 mg NW300EMCBD administered orally as 2 x 300 mg capsules following a HFHC meal;
• Regimen B: 900 mg NW300EMCBD administered orally as 3 x 300 mg capsules following a HFHC meal;
• Regimen C: 25 mg/kg Epidyolex solution administered orally as 2 x 12.5 mg/kg doses separated by 12 hours, each following a HFHC meal.
There will be a minimum 25-day washout period between the dosing visit (D1) of each treatment

period.
For each treatment period, participants will be required to stay at the clinical research site from the day before dosing until the completion of study activities on D5 (inpatient period: D-1 to D5). Participants will then be required to return to the clinical research site for scheduled outpatient visits until the end of the given treatment period (outpatient period; D6 to D9). Participants will be required to return to the clinical research site for the EOSV 25 days after the final dosing visit (i.e., 25 days after D1 of the third treatment period).
Trial participation will last approximately 105 days (i.e., max. 30-day screening period and 3 x approximately 25-day treatment periods) and involve a total of 29 visits (including 5 x visits per inpatient period per treatment period).

What are the possible benefits and risks of participating?
A large number of studies using doses of up to 3000 mg per day have reported CBD as being safe and generally well tolerated with no serious or severe adverse events. Additionally, no effects on physiological parameters such as blood pressure, body temperature, heart rate, or psychomotor functioning have been reported. No effects on psychological functioning other than mild sedation have been reported.
In large multisite trials the most common adverse events reported have included fatigue, gastrointestinal symptoms, and sleep disturbances. A previous proof-of-concept study conducted by the Sponsor concluded that CBD was tolerated as well as placebo, with the exception of slightly more frequent reports of mild sedation.
Adverse events will be monitored from D1 to D9 of each treatment period.
The trial procedures involve blood draws to assess pharmacokinetic parameters. Venepuncture carries minimal risks but should be acknowledged. Participants may experience momentary discomfort or pain at the site of needle insertion. Possible side effects include minor bruising or sweeling around the puncture site, bleeding, and, in rate cases, infection at the puncture site. Some individuals may experience dizziness, light-heartedness, or fainting during or immediately after the blood draw. All blood samples will be collected by trained medical professionals using sterile techniques to minimise these risks. Participants will be monitored during and after the procedure, and appropriate measures will be taken to ensure their safety and comfort.

Where is the study run from?
Fortrea Clinical Research Unit Limited (UK)

When is the study starting and how long is it expected to run for?
February 2025 to February 2026

Who is funding the study?
NW PharmaTech (UK)

Who is the main contact?
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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1011359

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NWPharma_CH_001

Study information

Scientific Title
A phase 1 study to assess the safety and pharmacokinetics of novel cannabidiol (CBD) soft-gel capsule formulation (NW300EMCBD) in healthy subjects

Study objectives
Primary objective:
1. To compare the pharmacokinetics of NW300EMCBD versus the comparator Epidyolex.

Secondary objectives:
2. To compare additional pharmacokinetics parameters of NW300EMCBD versus the comparator Epidyolex to provide mechanistic understanding of the PK.
3. To investigate the safety and tolerability of single doses of NW300EMCBD administered at two different dose levels in separate treatment periods versus the comparator Epidyolex.
4. To investigate the pharmacodynamics of single doses of NW300EMCBD versus the comparator Epidyolex.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/08/2025, London - Riverside Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8150 ; riverside.rec@hra.nhs.net), ref: 25/LO/0159

Study design
Interventional randomized crossover controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

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
Healthy volunteers. Intended indication is Clinical High Risk for Psychosis (CHR-P).

Interventions
Fourteen participants will be enrolled into the study (to provide a minimum of 12 evaluable participants).

Participants will receive the following dose regimens in a randomised order across 3 treatment periods:
• Regimen A: 600 mg NW300EMCBD administered orally as 2 x 300 mg capsules following a high-fat, high-calorie (HFHC) meal;
• Regimen B: 900 mg NW300EMCBD administered orally as 3 x 300 mg capsules following a HFHC meal;
• Regimen C: 25 mg/kg Epidyolex solution administered orally as 2 x 12.5 mg/kg doses separated by 12 hours, each following a HFHC meal.

There will be a minimum 25-day washout period between the dosing visit (D1) of each treatment period.

For each treatment period, participants will be required to stay at the clinical research site from the day before dosing until the completion of study activities on D5 (inpatient period: D-1 to D5). Participants will then be required to return to the clinical research site for scheduled outpatient visits until the end of the given treatment period (outpatient period; D6 to D9).

Participants will be required to return to the clinical research site for the end of study visit (EOSV) 25 days after the final dosing visit (i.e., 25 days after D1 of the third treatment period).

Trial participation will last approximately 105 days (i.e., max. 30-day screening period; 3 x approximately 25-day treatment periods) and involve a total of 29 visits (including 5 x visits per inpatient period per treatment period).

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacodynamic, Bioequivalence, Dose response

Phase
Phase I

Drug/device/biological/vaccine name(s)
Encapsulated Micellar Cannabinoid [Cannabidiol] NW300EMCBD, Epidyolex

Primary outcome measure
CBD, 7-OH-CBD, and 7-COOH-CBD pharmacokinetics parameters: Cmax, Tmax, AUCt, AUCinf, t1 /2; Cmax/D, AUCt/D, AUCinf/D (pre-dose and at 15, 30, 45, 60, 80, 100, 120, 150 min, 3, 4, 5, 6, 9, 12, 24, 48, 72, 96, 120, 144, 168, and 192 h post-dose for Regimen A and Regimen B; pre-dose and at 15, 30, 45, 60, 80, 100, 120, 150 min, 3, 4, 5, 6, 9, 12 h post-first dose and 15, 30, 45, 60, 80, 100, 120, 150 min, 3, 4, 6, 12, 24, 48, 72, 96, 120, 144, 168, and 192 h post-second dose for Regimen C).

Secondary outcome measures
1. CBD, 7-OH-CBD, and 7-COOH-CBD pharmacokinetics parameters: CL/F, Vz/F, Kel (pre-dose and at 15, 30, 45, 60, 80, 100, 120, 150 min, 3, 4, 5, 6, 9, 12, 24, 48, 72, 96, 120, 144, 168, and 192 h post-dose for Regimen A and Regimen B; pre-dose and at 15, 30, 45, 60, 80, 100, 120, 150 min, 3, 4, 5, 6, 9, 12 h post-first dose and 15, 30, 45, 60, 80, 100, 120, 150 min, 3, 4, 6, 12, 24, 48, 72, 96, 120, 144, 168, and 192 h post-second dose for Regimen C).
2. All reported adverse events using MedDRA V27 or above codes (from D1 to D9 of each treatment period and at the EOSV).
3. Changes from pre-dose baseline in laboratory findings after administration of oral doses of NW300EMCBD and Epidyolex (pre-dose and at 4, 24, 72, and 192 h post-dose for Regimen A and Regimen B; pre-dose, 4 h post-first dose, and at 4, 12, 24, 72, and 192 h post-second dose for Regimen C; and at the EOSV).
4. Changes from pre-dose baseline in vital signs over 192 hrs post-administration of oral doses of NW300EMCBD and Epidyolex (pre-dose and at 1, 2, 4, 8, 24, 48, 72, 96, 120, 144, 168, and 192 h post-dose for Regimen A and Regimen B; pre-dose and at 1, 2, 4, and 8 h post-first dose and at 1,

2, 4, 12, 24, 48, 72, 96, 120, 144, 168, and 192 h post-second dose for Regimen C; and at the EOSV).
5. Change from pre-dose baseline in ECG parameters (pre-dose and at 4 h post-dose for Regimen A, Regimen B, and Regimen C; and at the EOSV).
6. Change in gastrointestinal symptoms (pre-dose and at 3 and 24 h post-dose for Regimen A and Regimen B; pre-dose, 3 h post-first dose, and 12 and 24 h post-second dose for Regimen C).
7. Change in ColumbiaSuicide Severity Rating Scale (CSSRS) score (at screening; pre-dose and at 3, 24, 96, and 192 h post-dose for Regimen A and Regimen B; pre-dose, 3 h post-first dose, and at 12, 24, 96, and 192 h post-second dose for Regimen C; and at the EOSV).
8. Change in VAMS subscales (mental sedation subscale, tranquilisation and calming effects subscale, physical sedation subscale, other feelings and effects subscale) and in strength and desirability of drug effects, using the Drug Experience Questionnaire (DEQ-5) (pre dose and at 3 h post-dose for Regimen A, Regimen B, and Regimen C).

Overall study start date
03/02/2025

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. Healthy male or female volunteers.
2. Age range between 18 and 55 years old.
3. Weight at least 50kg and have a body mass index (BMI) between 19 and 30 kg/m2 at screening.
4. Willingness to comply with and complete all study procedures, including consuming the protocol specified HFHC meal in 30 minutes.
5. In good health, as determined by no clinically significant findings from medical history, 12-lead ECG and vital signs measurements, and clinical laboratory evaluations at screening and check-in, and from the physical examination at check-in, as assessed by the investigator or designee.
6. Abstinence from consuming St John’s wort, grapefruit (juice), alcohol or tobacco and nicotine products for at least 72 hours prior to dosing and throughout treatment period.
7. Abstinence from caffeine for the duration of the in-clinic confinement period, including all dosing days. Caffeinated beverages and products will not be available on site.
8. Capable and willing to comply with protocol requirements during the study.
9. Participant is willing and able to give informed consent for participation in the study.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex

Both

Target number of participants
14

Key exclusion criteria
1. Participation in a research trial within 90 days prior to Day 1, or 5 elimination half-lives prior to Day 1 (whichever is longer), or throughout the study.
2. Use of cannabis products, including hemp, in any form (including medication, oils, edibles or drinks) during the last 28 days before screening.
3. History of hypersensitivity or allergy to CBD oil, sesame oil, hemp or any other cannabinoid products, or any of the items that could be included in the standardized meals/snacks.
4. Using any regular medication in the 28 days prior to screening and throughout the study (as required doses of paracetamol or non-steroidal anti-inflammatory drugs (NSAIDs) are permitted).
5. Abnormal screening sample: clinically significant liver, renal or haematological abnormalities, including total Bilirubin, ALT or AST > the upper limit of normal (ULN).
6. Positive screening test indicating active infection with HIV, hepatitis B virus or hepatitis C virus. Participants with evidence of past HBV infection and complete recovery may be eligible, at the discretion of the Investigator, provided liver function tests are within normal limits and there is no evidence of active infection.
7. Positive urine drug sample, including THC, at screening and, baseline excluding THC at post-dose.
8. Positive alcohol breathalyser test at screening and throughout the study.
9. Any suicidal ideation or behaviour in the past 12 months as assessed by responses to Columbia Suicidal Severity Rating questionnaire at screening.
10. Any history of mental disorder including major depressive disorder, bipolar disorder, psychosis, and any current substance use disorder, including alcohol and tobacco use disorder.
11. Any self-reported, observed or assessed medical condition that might put the subject at risk according to the physician’s opinion.
12. Any significant previous or current history of comorbidities capable of significantly altering the absorption, metabolism, or elimination of drugs; of constituting a risk when taking the investigational product; or of interfering with the interpretation of data.
13. Participants with a sitting blood pressure at screening, after resting for 5 minutes, higher than 140/90 mmHg or lower than 90/50 mmHg.
14. Blood donation or loss (eg surgery) over 200 ml in 3 months prior to screening and throughout study (menstruation is acceptable).
15. Male participants not willing to use contraceptive methods throughout the study.
16. Female participants who are pregnant (positive B-hCG urine test), lactating or breastfeeding.
17. Female participants of childbearing potential* and not willing to use highly effective contraceptive methods** at screening or throughout the study.
*Defined as females who have experienced menarche and are not surgically sterilised (eg hysterectomy, bilateral salpingectomy) or post-menopausal.
**Highly effective methods of birth control are those with a failure rate <1% per year and include combined oestrogen and progesterone hormonal contraception, progestogen-only hormonal contraception, intrauterine devices (IUD), intrauterine hormone-releasing systems (IUS) and vasectomised partner.
18. Participants with planned surgical or medical treatment requiring hospitalisation during the study.
19. Employees or family members of the Sponsor.
20. Participant unable to communicate reliably with research team.
21. Participant is not able to swallow capsules.

22. Subject unable or unwilling to consume the protocol specified HFHC meal required by the trial protocol and/or the soft gel capsules, which contain gelatine of bovine origin, and/or Epidyolex which contains sesame oil and ethanol.
23. Subjects with alcohol consumption > 14U/ week.

Date of first enrolment
26/08/2025

Date of final enrolment
25/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Fortrea Clinical Research Unit Limited
Drapers
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Sponsor information

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
NW PharmaTech

Results and Publications

Publication and dissemination plan
Submission to regulatory authorities

Intention to publish date
26/08/2026

Individual participant data (IPD) sharing plan
There are no plans to share the study data with others.

IPD sharing plan summary
Not expected to be made available