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Exploring cannabidiol's impact on behaviour in adults with intellectual disabilities and epilepsy (CANABID-LD)

Submission date
03/11/2025

Recruitment status
Recruiting

Registration date
02/02/2026

Overall study status
Ongoing

Last Edited
02/02/2026

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Some people with epilepsy also have intellectual disability (ID), which can affect how they learn, communicate, and manage everyday tasks. Certain types of epilepsy—Dravet syndrome (DS), Lennox-Gastaut syndrome (LGS), and tuberous sclerosis complex (TSC)—often come with both ID and challenging behaviours. These behaviours can be difficult to manage and may affect the person's safety and quality of life. There aren't many effective medicines to help with these behaviours. Cannabidiol (Epidyolex) is a medicine already approved to help control seizures in people with DS, LGS or TSC. This study aims to find out whether Epidyolex might also help reduce challenging behaviours and improve quality of life.

Who can participate?
People aged 16 or older who have a confirmed diagnosis of DS, LGS or TSC, along with an intellectual disability, and who are about to start taking Epidyolex for seizures. Participants must be under the care of specialist NHS services and have a caregiver who can help with the study. Consent will be given either by the participant or by someone who knows them well and can speak on their behalf.

What does the study involve?
This is an observational study, which means participants will not be asked to take any extra medication or change their usual care. The study will follow participants over six months, with check-ins at the start, after three months, and after six months. All data will be collected remotely, with help from the participant's caregiver. Researchers will look at changes in behaviour, seizure frequency, and quality of life.

What are the possible benefits and risks of participating?
There may be no direct benefit, but the study could help improve future care and treatment options for people with epilepsy and ID. Because the study does not involve any changes to treatment or extra clinic visits, risks are minimal.

Where is the study run from?
University of Plymouth (UK)

When is the study starting and how long is it expected to run for?
October 2025 to January 2027

Who is funding the study?
Jazz Pharmaceuticals (UK)

Who is the main contact?
canabid.penctu@plymouth.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
330775

Grant Code
2023-IST-300020

Central Portfolio Management System (CPMS)
57056

Study information

Scientific Title
CANnabidiol impact on challenging behaviour in Adults with Intellectual Disability with Lennox-Gastaut syndrome, Dravet syndrome and tuberous sclerosis complex (CANABID-LD): a prospective observational cohort study

Acronym
CANABID-LD

Study objectives
Primary objective: To determine if cannabidiol affects challenging behaviours in patients with ID and epilepsy, determined by changes to the ABC-2 Irritability subscale score between baseline and 180 days post initiation of treatment.

Secondary objectives:
1. To determine if cannabidiol affects other behavioural, clinical and psychological outcomes associated with cannabidiol prescribing at 90 days and 180 days post-treatment initiation.
2. To explore the association between cannabidiol dose and change in challenging behaviour.
3. To determine any changes in seizure type/frequency at 90 days and 180 days post-treatment initiation.
4. To test methods to economically evaluate the provision of cannabidiol and its impact on quality of life.
5. To explore differences in changes to challenging behaviour between those who meet the threshold for moderate to severe challenging behaviour at baseline (Group A) and those who do not meet threshold for moderate to severe challenging behaviour - i.e., no challenging behaviour or mild challenging behaviour at baseline (Group B).
6. To gain a deeper understanding of participant/primary caregiver/clinician's experience of cannabidiol on challenging behaviours and seizures, including treatment acceptability (WP2).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/08/2025, Yorkshire & The Humber - Leeds East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8029; leedseast.rec@hra.nhs.uk), ref: 25/YH/0142

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adults with Intellectual Disability with Lennox-Gastaut syndrome, Dravet syndrome and tuberous sclerosis complex

Interventions
CANABID-LD is a prospective observational cohort study, with an embedded qualitative component, to examine the impact of cannabidiol on challenging behaviour, seizure type /frequency and quality of life when prescribed for clinical indicated reason of seizure management in people with LGS/DS/TSC.

The overall protocol aim is to examine the relationship of prescribed cannabidiol for pharmaco-resistant seizures on challenging behaviours, seizure frequency and quality of life, among adults with LGS, DS or TSC with co-occurring ID.

This study is separated into two Work Packages (WP1 and WP2). WP1 refers to the observational cohort study. 60 participants will be recruited who are going to prospectively commence treatment with Epidyolex. Data will be collected at three time points over a 6-month period (baseline, 3-month post-treatment initiation and 6-months post-treatment initiation). Consent and baseline data collection may take place face-to-face, if a routine clinic visit is scheduled, or remotely. Baseline data, including diagnosis, ID classification, demographics, medications and co-morbidities, will be collected using routine medical record information. In addition, three questionnaires/scales will be administered to the participant's primary caregiver with support of the researcher/clinician (EQ-5D-5L, ABC-2 and HONOS-ID) and data will be asked about the participant's seizure type/frequency. The primary caregiver will be contacted via telephone again at the 3-month and 6-month, where the same questionnaires/scales will be administered (EQ-5D-5L, ABC-2 and HONOS-ID) and they will be asked about any medication changes, seizure type/frequency and any key events that may have significantly impacted behaviour. The caregiver will be provided with copies of the questionnaires and a seizure and key event record to support accurate data collection.

WP2 is an embedded qualitative component. 15 primary caregivers of participants involved in WP1 will be invited to take part in a 60 minutes semi-structured interview to discuss the participant's experience with Epidyolex. The primary caregiver will have the option on the consultee declaration form to indicate that they are happy to be contacted about the additional interview study. Interviews will take place at the end of the participant's time on the study (6-months after treatment initiation) remotely, via video-conferencing or Microsoft Teams. 10 clinicians will also be interviewed, one from each site, who have been involved in the study and have experience with Epidyolex prescribing for DS, LGS and TSC patients. These will also take place via video-conferencing or telephone call in a semi-structured format. This is to obtain information about the clinician experience with Epidyolex.

Intervention Type
Other

Primary outcome(s)
Aberrant Behaviour Checklist-Second edition (ABC-2) Irritability subscale at baseline, 180 days

Key secondary outcome(s))
1. Health status is measured using the Health of the Nation Outcome Scale for People with Intellectual Difficulties (HONOS-ID) at baseline, 90 days, and 180 days
2. Clinical global impression is measured using the Clinical Global Impression (CGI) scale at 180 days or routine follow-up visit
3. Aberrant behavior is measured using the Aberrant Behavior Checklist-2 (ABC-2) at baseline, 90 days, and 180 days
4. Cannabidiol daily dose (mg/kg/day) is measured using treatment records at baseline, 90 days, and 180 days
5. Seizure type and frequency are measured using seizure diaries or clinical records at baseline, 90 days, and 180 days
6. Health-related quality of life is measured using the EQ-5D-5L Proxy Version 2 questionnaire at baseline, 90 days, and 180 days
7. Resource utilization is measured using the resource use questionnaire at baseline, 90 days,

and 180 days
8. Semi-structured qualitative data on participant experience is measured using interviews at 180 days after treatment initiation

Completion date
31/01/2027

Eligibility

Key inclusion criteria
1. ≥ 16 years of age at the time of enrolment.
2. Confirmed clinical diagnosis of Lennox-Gastaut Syndrome (LGS), Dravet Syndrome (DS), or Tuberous Sclerosis Complex (TSC).
3. Confirmed clinical diagnosis of an Intellectual Disability (ID).
4. Patient meets the clinical criteria to be prescribed regulatory approved cannabidiol (Epidyolex) for seizure management, as per clinician judgment.
5. Patient is scheduled to start, but has not yet commenced, cannabidiol treatment.
6. Participant has the capacity to be able to provide consent for themselves, or a personal /professional consultee is able to provide an opinion on the views and feelings of the participant.
7. Participant has a primary caregiver who is willing and able to complete caregiver-reported outcome measures.
8. Willing and able to complete all scheduled follow-ups.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Patients previously or already on prescribed regulatory approved cannabidiol.

Date of first enrolment
10/10/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Swansea Bay University Local Health Board
Tonna Hospital
Tonna Uchaf
Tonna
Neath
Wales
SA11 3LX

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street

Leeds
England
LS9 7TF

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
England
NW1 2PG

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
England
NW3 2QG

Study participating centre
Birmingham Community Healthcare NHS Foundation Trust
3 Priestley Wharf
Holt Street
Birmingham Science Park, Aston
Birmingham
England
B7 4BN

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
The Walton Centre NHS Foundation Trust
Lower Lane
Fazakerley
Liverpool

England
L9 7LJ

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
England
BA1 3NG

Sponsor information

Organisation
University of Plymouth

ROR
https://ror.org/008n7pv89

Funder(s)

Funder type
Industry

Funder Name
Jazz Pharmaceuticals

Alternative Name(s)
Jazz Pharmaceuticals plc, Greenwich Biosciences, Jazz Pharmaceuticals, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (PEARL, University of Plymouth open access research repository. Fully anonymised data will be available at the end of the study for a minimum of ten years. Participant's informed consent is received in relating to data processing and storage arrangements).

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.2	22/10/2025	24/11/2025	No	No