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ENDOCAN-1: A study to see if CBD (cannabinoid) can help with endometriosis-related pain

Submission date	Recruitment status	[X] Prospectively registered
07/08/2025	Not yet recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/03/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
03/03/2026	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study, funded by the Chief Scientist Office (CSO) will use a solution called MRX-1 which is a cannabinoid solution that does not contain THC which we will use to see if it reduces pain in patients with endometriosis. Endometriosis is a condition that affects 1 in 10 women or those assigned female at birth and causes pain, infertility and can reduce quality of life. At the moment available drug treatments have unacceptable side effects and are often hormonal and are contraceptive. There is an unmet need to find new treatments . Cannabinoids have been shown to be effective in other pain conditions.

Who can participate?
We will recruit 100 women over a period of 18 months from NHS Lothian and NHS Grampian.

What does the study involve?
This study will involve 5 hospital visits over a period of 17-18 weeks. Once eligibility has been confirmed the participant will be selected by chance (randomised) to have either the trial solution or placebo solution. The solution will be dosed according to the participant's weight and the dose can be increased weekly up to a maximum of 6.25mg/kg twice daily. They will take the solution for a 12 week period. We will collect questionnaires to assess pain scores and quality of life information. This study will help us develop a larger multi centre study. We will also ask participants in Edinburgh to wear a smartwatch during their participation (optional).

What are the possible benefits and risks of participating?
Participants may or may not benefit from taking part in this trial, however the results from this trial might help to improve the healthcare of patients with endometriosis in the future. Participants may also feel some improvement in their pain symptoms.
The patient might experience some side effects caused by the study solution. If they experience intolerable side effects they can either reduce the dose they are taking or stop.
Questionnaires where possible can be completed online at home to reduce the time burden on

patients.
The participants will have blood samples taken which might cause discomfort and bruising but this will be taken by a trained member of the research team.

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

When is the study starting and how long is it expected to run for?
April 2026 to March 2028

Who is funding the study?
Chief Scientist Office, Scottish Government Health and Social Care Directorate (UK)

Who is the main contact?
ETMT@ed.ac.uk

Contact information

Type(s)
Public

Contact name
None - ENDOCAN-1 Trial Team

Contact details
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Type(s)
Principal investigator, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
1010848

Protocol serial number
AC24037

Study information

Scientific Title
ENDOCAN-1: A feasibility randomised controlled trial of the efficacy of a cannabinoid oral solution in the management of endometriosis-associated pain

Acronym
ENDOCAN-1

Study objectives
Primary objective:
To determine the eligibility, recruitment and retention rates

Secondary objectives:
1. To estimate the effectiveness of CBD solution to alleviate pain in women with endometriosis
2. To estimate the effectiveness of CBD solution to improve quality of life
3. To assess safety of CBD solution
4. To estimate the impact of CBD solution on analgesic use
5. To estimate compliance with treatment over a 12 week period
6. To estimate patient satisfaction with treatment
7. To estimate acceptability of proposed trial
8. To estimate cost implications of CBD treatment
9. To determine if there is a change to inflammatory markers expression

Tertiary objective:
To determine whether objective data collected via smartwatch correlates with patient reported outcomes

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/02/2026, - (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; a@a), ref: -

Study design
Interventional double blind randomized parallel group placebo controlled trial

Primary study design
Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied
Endometriosis

Interventions
Participants will be randomised into one of two treatment arms, via an online randomisation tool.
CBD arm: participants in the active arm will be given oral CBD solution for 12 weeks duration. The starting dose will be a solution of 0.5 mg/kg BID administered morning and evening and taken with food. The dose will be increased if there is ongoing pain and tolerable or no side effects, as per below:

Week Dose (mg/kg b.i.d)
1 0.5
2 1
3 2
4 3.25
5 4.75
6 6.25

A maximum dose of 6.25 mg/kg BID will be permitted.
At Week 6, participants will attend a research visit for re-supply.
After 12 weeks of treatment, a follow up visit will be carried out 10 days after end of treatment.

Placebo arm: Identical dosing regime as above for 12 weeks.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
MRX1 [Cannabidiol]

Primary outcome(s)
Proportion of those eligible who are consented and recruited (screening logs) from first screening, the proportion who are eligible and randomised after the screening period and those randomised who are retained (completing the 12 week outcome measures) after 12 weeks

Key secondary outcome(s))
Measured at weeks 1-13:
1. Pain (NRS worst and average pain score, Pain DETECT, pain domain of EHP-30)
2. Quality of life (EHP30, Fatigue Severity Scale (FSS), Fibromyalgia scale, The Sleep Timing Questionnaire (STQ), Pain Catastrophising Questionnaire (PCQ), Gastrointestinal Symptom Rating Scale (GSRS), Patient Global Impression of Change (PGIC) questionnaires)
3. Safety (side effects, adverse events, full blood count and clinical chemistry, patient health questionnaire (PHQ-9))
4. Analgesic use (participant-reported)
5. Compliance with medication (dose escalation, self-reported and volume returned)
6. Acceptability of trial and patient satisfaction (assessed by questionnaire and optional qualitative interview at the end of study)
7. Health economic (EQ-5D-5L, medication use, healthcare (resource) visits)
8. Measure inflammatory markers in serum and plasma samples

Tertiary outcome:
Comparison of movement, ambient temperature and light (which indicates activity and sleep) collected with a smartwatch, with responses captured in the FFS and STQ questionnaires

Completion date
31/03/2028

Eligibility

Key inclusion criteria
1. Women or assigned female at birth
2. Aged 18 years or over
3. Endometriosis identified at laparoscopy or imaging, performed within the last ten years
4. Self reported pelvic pain for more than six months
5. Weekly worst pain score of at least four on a numerical rating scale (NRS) on two or more occasions over the four weeks prior to randomisation
6. Willing not to take additional cannabinoids during the trial period
7. Willing to use effective contraception throughout the trial (if needed)
8. Willing and able to give informed consent
9. Willing to be contacted by text message

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Pregnant, breastfeeding or actively trying to get pregnant
2. Post-menopausal (no periods for >12 months and not taking hormonal treatments to prevent periods, or bilateral oophorectomy performed)
3. Suicidal thoughts or severe depression within the past year
4. Current use (or within the last 1 month) of other cannabinoid or cannabis products, determined by urine dipstick test
5. Chronic alcohol abuse

6. History of severe liver disease (Alanine transaminase (ALT) and/or aspartate aminotransferase (AST) more than 3-times the upper limit of normal (ULN)) and bilirubin greater than 2 times the ULN, Or moderate to severe hepatic impairment (Child-Pugh class B or C)
7. Concomitant use of Sodium Valproate, Clobazam, Stiripentol, Everolimus
8. Hypersensitivity to any of the components of the formulation as defined in the IB
9. Taking part in another CTIMP or interventional non-CTIMP study

Date of first enrolment
01/04/2026

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Scotland
EH16 4SA

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
Scotland
AB25 2ZN

Sponsor information

Organisation
University of Edinburgh and NHS Lothian

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date