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Determining the role of synthetic cannabinoids in eye pressure and tolerability measurements

Submission date 31/03/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 01/04/2026	**Overall study status** Ongoing	
Last Edited 29/04/2026	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Glaucoma is a leading cause of irreversible blindness. The term ‘glaucoma’ refers to a group of heterogenous pathologies that result in excavation of the eye, progressive damage to the retinal ganglion cells (RGCs), optic nerve damage, and subsequent visual impairment. There are currently no treatments that cure glaucoma; however, medications that reduce intraocular pressure (IOP) may slow or prevent disease progression. There have been several clinical studies that have assessed synthetic cannabinoids on glaucoma. Many of these have shown significant lowering of IOP however the effects can be short lived and the drugs have been shown to cause side effects that patients were not able to tolerate including nausea, confusion, euphoria and dizziness.

ART27.13 is a synthetic, peripherally selective cannabinoid with minimal brain penetration therefore it should not cause the unwanted side effects seen in other cannabinoids. This trial will investigate the safety and tolerability of treatment with capsulated ART27.13 at a dose of 600ug over a three week treatment period and whether is reduces IOP.

Who can participate?
Males aged 40 years or older and females aged 55 years or older with ocular hypertension or early primary open angle glaucoma.

What does the study involve?
Any participant who is already on topical glaucoma treatment will undergo a four-week wash out period before baseline and will not use any glaucoma drops during the trial. The study will run as a crossover design in which one half of the recruited participants will be randomised to receive ART27.13 or placebo for three weeks. Following this, patients who initially received ART27.13 will then be switched to placebo for three weeks (and vice versa) following a three-week washout period. This design was chosen to maximise the efficiency of the study, ensuring that data on ART27.13 is acquired from all study participants. The placebo will be in capsule form, identical in appearance to ART27.13, to minimise the risk of bias.

Participants will have screening and baseline tests done before receiving any treatment including blood tests, physical exam and eye exams. One week after receiving the first

treatment (either ART27.13 or placebo), the research staff will phone the participant to ask questions around how they are feeling. Participants will come back to the clinic after the three weeks of treatment where they will complete a questionnaire and have bloods taken along with a physical exam and eye exams to measure IOP. After a three week wash out with no treatment, participants will come back to the clinic to have more tests and receive their second treatment (either placebo or ART27.13). Another phone call will be made by research staff one week after starting the second treatment. Participants will come back to clinic after three weeks of the second treatment to have post-treatment tests carried out including blood tests, physical exam and eye exams. A final phone call check up will be made 4 weeks after the clinic visit.

What are the possible benefits and risks of participating?
New research is vital to developing new treatments for diseases, especially for glaucoma. However, as this is a new
treatment we cannot be certain of the outcome and participants may experience side effects such as; increased IOP, dizziness, postural dizziness, nausea, low blood pressure (hypotension), headache, dry mouth, fatigue, drowsiness (somnolence), back pain, malaise, and changes in blood tests looking at liver function. ART27.13 may also stimulate appetite and lead to weight gain. As side effects of ART27.13 include dizziness and somnolence caution should be taken around driving or operating heavy machinery. Participants cannot drive or operate heavy machinery in the first 4 weeks each time of start taking the medication.

Where is the study run from?
Northern Ireland Clinical Research Facility (NICRF), Belfast City Hospital

When is the study starting and how long is it expected to run for?
April 2026 to May 2027

Who is funding the study?
Glaucoma UK and Public Health Agency (PHA), Health and Social Care (HSC) Research & Development Division, Northern Ireland

Who is the main contact?
Professor Augusto Azuara-Blanco (a.azuara-blanco@qub.ac.uk)
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Additional identifiers

Integrated Research Application System (IRAS)
1010931

Study information

Scientific Title
A pilot, randomised, cross-over study to determine the effects of an oral, peripherally selective, synthetic cannabinoid ART27.13 on intraocular pressure

Acronym
DREAM

Study objectives
1. To evaluate the IOP lowering efficacy of ART27.13
2. To assess the safety and tolerability of ART27.13

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/02/2026, North East – Newcastle and North Tyneside 2 (2 Redman Place Stratford, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 207 104 8086; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 25/NE/0218

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Crossover

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Ocular hypertension or early primary open angle glaucoma

Interventions
The investigational medicinal product (IMP) will be ART27.13, a synthetic, peripherally selective cannabinoid which is under development by Artelo Biosciences. The study will run as a crossover design in which one half of the recruited participants will be randomised to receive ART27.13 or placebo for three weeks. Following this, patients who initially received ART27.13 will then be switched to placebo for three weeks (and vice versa) following a three-week washout period. This design was chosen to maximise the efficiency of the study, ensuring that data on ART27.13 is acquired from all study participants. The placebo will be in capsule form, identical in appearance to ART27.13, to minimise the risk of bias.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
ART27.13

Primary outcome(s)
1. Intraocular pressure (IOP) measured using Goldmann Applanation Tonometry (GAT) as mmHg at Screening, Baseline (if washout of previous IOP reducing drug needed), 3 weeks after first treatment (either ART27.13 or placebo), after 3 week washout of first treatment, after 3 weeks of second treatment (either placebo or ART27.13)

Key secondary outcome(s))
1. Safety measured using Incidence of Adverse Events (AEs)/Serious Adverse Events (SAEs) at Screening, baseline, Day 7, Day 21, day 42, Day 49, Day 63 and Day 91

2. Tolerability of ART27.13 in relation to effect on mood measured using VAMS Questionnaire at Baseline, Day 21, Day 42, Day 63

3. The abuse potential of ART27.13 measured using Drug Abuse Potential Questionnaire at Day 21 and Day 63

Completion date
28/05/2027

Eligibility

Key inclusion criteria
1. Age ≥ 40 years for males, ≥ 55 years for females
2. Ocular hypertension or early primary open angle glaucoma (visual field loss, less severe than -6 dB in a standard 24-2 Humphrey visual field test)
3. IOP between 20 and 35 mmHg inclusive

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Any other clinically significant ocular disease in either eye
2. Current liver disease or laboratory results with elevated levels of liver transaminases (AST or ALT >3 x upper limit of normal (ULN) at screening visit)
3. Renal failure (eGFR <30 mL/min/1.73m^2 at screening visit)
4. Heart disease (e.g. myocardial infarction or arrhythmia)
5. Diagnosed with cancer in the last 12 months (with exception of non-melanoma skin cancer)
6. Prior ocular laser treatment within previous 12 months of enrolment
7. Prior surgical treatment for glaucoma
8. Intraocular surgery within previous 12 months of enrolment
9. Use of cannabinoids for other purposes within 3 months of enrolment (with the exception of cannabidiol (CBD))
10. Woman of childbearing potential i.e has had a menstrual cycle in the last 12 months or has not been permanently sterilised.
11. Male participants with sexual partners who have not agreed to use a condom during treatment and for 1 month after the last dose is administered.
12. Current use of systemic beta-blockers
13. Within 4 weeks prior to enrolment been on or expected to be on medications that are known to be strong cytochrome P450 CYP3A4 inhibitors or inducers
14. Within 4 weeks prior to enrolment been on or expected to be on medications that are known to be P-glycoprotein (PgP) Inhibitors or Substrates
15. Any clinical condition that, in the investigator’s opinion, would make the participant unsuitable for the trial
16. Non-English speaking patients or those who do not adequately understand verbal or written

information
17. Any known allergy to the active ingredient or excipients
18. History of any recreational or illicit drug use, alcohol misuse, or other drug misuse within the last 24 months.
19. Any history of depression in the last five years or current use of anti-depressant medication.
20. Not agreed to abstain from driving or operating heavy machinery for the first 4 weeks of each treatment cycle or longer if AEs warrant.
21. Total serum Bilirubin > 1.5 x upper limit of normal
22. Any history of suicidal behaviour or serious suicidal ideation, defined as Category 4 or greater on the Columbia Suicide Severity Rating Scale (C-SSRS) at screening.
23. Declined consent

Date of first enrolment
29/05/2026

Date of final enrolment
30/10/2026

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Northern Ireland Clinical Research Facility
Belfast City Hospital
Lisburn Road
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Northern Ireland
BT9 7AB

Sponsor information

Organisation
Belfast Health and Social Care Trust

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type

Funder Name
Glaucoma UK

Funder Name
Public Health Agency (PHA), Health and Social Care (HSC) Research & Development Division, Northern Ireland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available