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PARTICIPANT INFORMATION SHEET

IRAS ID: 1010931

Determining the Role of Synthetic Cannabinoids in Eye Pressure And Tolerability Measurements (DREAM)

We would like to invite you to take part in our research study.

- Before you decide we would like you to understand why the research is being done and what it would involve for you.
- A member of the study team will go through this information sheet with you. Please ask questions about anything that might not be clear.
- Please take time to read the information carefully and discuss it with family and friends if you wish.

Thank you for your time to consider participation in the DREAM study

Why have you been invited to take part?

You are being invited to take part because you are at least 40 years old and have been diagnosed with ocular hypertension (raised eye pressure, but with no signs of glaucoma) or glaucoma. We aim to recruit 10 participants to take part in this study.

Why is this study being done?

The purpose of this study is to test that a new treatment for glaucoma works and is safe. Glaucoma is an eye disease which leads to a gradual loss of vision caused by damage to the nerve at the back of the eye. It is often caused by an increase in the pressure inside the eye. There are currently no treatments that will cure glaucoma, however eye drops, laser treatment or surgery are typically used to slow down damage to the nerve by lowering the pressure in the eye. Even with use of these treatments, some patients continue to lose their vision. It is therefore important to discover new treatments which can help prevent disease progression and vision loss.

A possible alternative is to use cannabinoids (related to the cannabis plant) taken by mouth. Research has shown that cannabinoid medications are effective at lowering eye pressure. The medication which is being tested in this study is called ART27.13. It is a synthetic (man-made) cannabinoid, which means that it acts in a similar way to chemicals which occur naturally in the cannabis plant but instead it is manufactured in a laboratory. ART27.13 is an oral cannabinoid which has been shown in previous research to have few side effects, meaning it should not have the same effects as the cannabis plant and does not have the same effects on the brain. Therefore, the aim of this study is to find out whether ART27.13 is effective at lowering eye pressure and to assess what patients think of it. If it is effective, this could provide a promising alternative treatment for

patients with glaucoma to reduce progression of the disease and prevent vision loss.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you agree to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You may still decide to withdraw your consent to take part at any time without giving a reason. If you decide not to take part, this will not affect your legal rights or healthcare at any time, now or in the future.

What will happen if I agree to take part in the DREAM study?

If you agree to take part in the DREAM study, you will be invited to attend a screening/baseline appointment at the Northern Ireland Clinical Research Facility (NICRF), Belfast City Hospital to check if you are suitable for the study. If you are suitable to take part, your participation will be for a period of up to 17 weeks. During this time you will be required to attend the NICRF on 4 or 5 occasions with each visit lasting between 2-3 hours.

You will not be paid for taking part in this study. However, you will receive £30 per study visit to cover any expenses.

Study Medication

Once we have determined that you are suitable for the study, you will receive either:

1. Placebo then active medication ART27.13 or
2. Active medication ART27.13 then placebo.

A placebo is a dummy drug that looks identical to the ART27.13 medication but which has no active ingredient. Neither you nor the study team will know which medication you have been assigned.

The total dose of medication you will be asked to take each time is 3 x 200 microgram (total dose 600 micrograms) capsules once

per day in the morning for a period of three weeks. Please store the study drug between 15^0C and 25^0C and protect from light, as indicated on the study drug label.

All medications (including prescription and over-the-counter medication), vitamin or mineral supplements, will be recorded if you agree to participate in the DREAM study. Whilst participating in the DREAM study, you will not be able to take some medications. ***Please contact the study team using the details at the end of this information leaflet prior to starting any new medication***. We will also advise your GP to contact the study team prior to prescribing you any new medication.

If you are currently taking medication to lower the pressure in your eye, you will be asked to stop taking this while you are taking part in DREAM. There will be a 4 week period called a wash out period where you will need to have stopped the medication before you can start on the study medication. However, if the pressure in your eyes increases, study medication may be stopped and your usual glaucoma treatment may be restarted by the study team. You will then return to where you normally receive your usual clinical care. Study medication will not be available to you at the end of the DREAM study.

The following procedures will be carried out at each of the study visits detailed below.

Visit	**Location**	**Procedures**
Screening/ Baseline	Hospital	• Written consent • Medical and eye history* • Physical exam[1] • Vital signs: heart rate, blood pressure and weight* • Eye health exam* • Electrocardiogram (ECG)[2]

		• Visual acuity[3] • Visual fields[4] • Eye pressure*[5] • A blood sample (approximately 10mls, or one tablespoon) for routine tests. • Complete two questionnaires asking about your feelings and mood[6]. • A 4 week wash out period may be required if you have already been taking medication that lowers eye pressure. If this is the case the points marked with * will need repeated at the hospital after the wash out • Medication will be provided in the form of capsules at the hospital visit
Week 1	Phone Call	• Ask about any side effects or changes to medication
Week 3	Hospital	• Medical and eye history review, including whether you have noticed any side effects from the study medication. • Physical exam: Heart rate, blood pressure and weight • Eye pressure • Blood samples for routine tests (approximately 10 mls, or one tablespoon) • Complete three questionnaires asking about how the

		medication makes you feel and your mood[6]. • You will be asked to return unused study medication at this visit. You will not receive any new medication at this visit.
Weeks 3 to 6	N/A	• You will not take any study medication for another 3 weeks. This is to ensure any medication remaining in your body is removed.
Week 6	Hospital	• The same procedures that were carried out at week 3 will be repeated • You will receive a new medication. As before, neither you nor the study team will know which medication you are receiving. • Complete a questionnaire asking about your feelings and mood[6].
Week 7	Phone Call	• Ask about any side effects or changes to medication
Week 9	Hospital	• We will repeat all of the tests we conducted at your screening with the exception of the visual fields test. • We will ask you to return any unused medication

		• Complete three questionnaires asking about your feelings and mood[6].
Week 13	Phone Call	• Ask about any side effects since stopping the medication. • Complete a questionnaire asking about your feelings and mood[6].

[1] The physical exam will involve a check of your head and neck, cardiovascular (heart), dermatological (skin), musculoskeletal (muscles and bones), respiratory (lungs), gastrointestinal (stomach and intestines), neurological systems and others if needed.

[2] This is a test which measures the electrical activity of the heart, including its rhythm, rate and overall function. Although ECGs are scheduled for screening/baseline and week 9 visits, additional ECGs may be carried out if the clinician feels they are required.

[3] This is a measure of how many letters you can read on an eye chart.

[4] This is a test of your peripheral vision which you may be familiar with from the glaucoma clinic or your local optometrist. The test will be completed in both eyes and will take around 20-30 minutes to complete. If you have completed a visual fields test in the last 6 months and the results are available, you will not be required to repeat this test at the screening/baseline visit.

[5] This is a measure of the pressure in your eye. At least two readings will be taken in each eye using a device which lightly touches your eye. This is the procedure routinely used in hospital clinics and your local optometrists. A drop of anaesthetic will be instilled into each eye before carrying out the procedure so that you will not feel anything.

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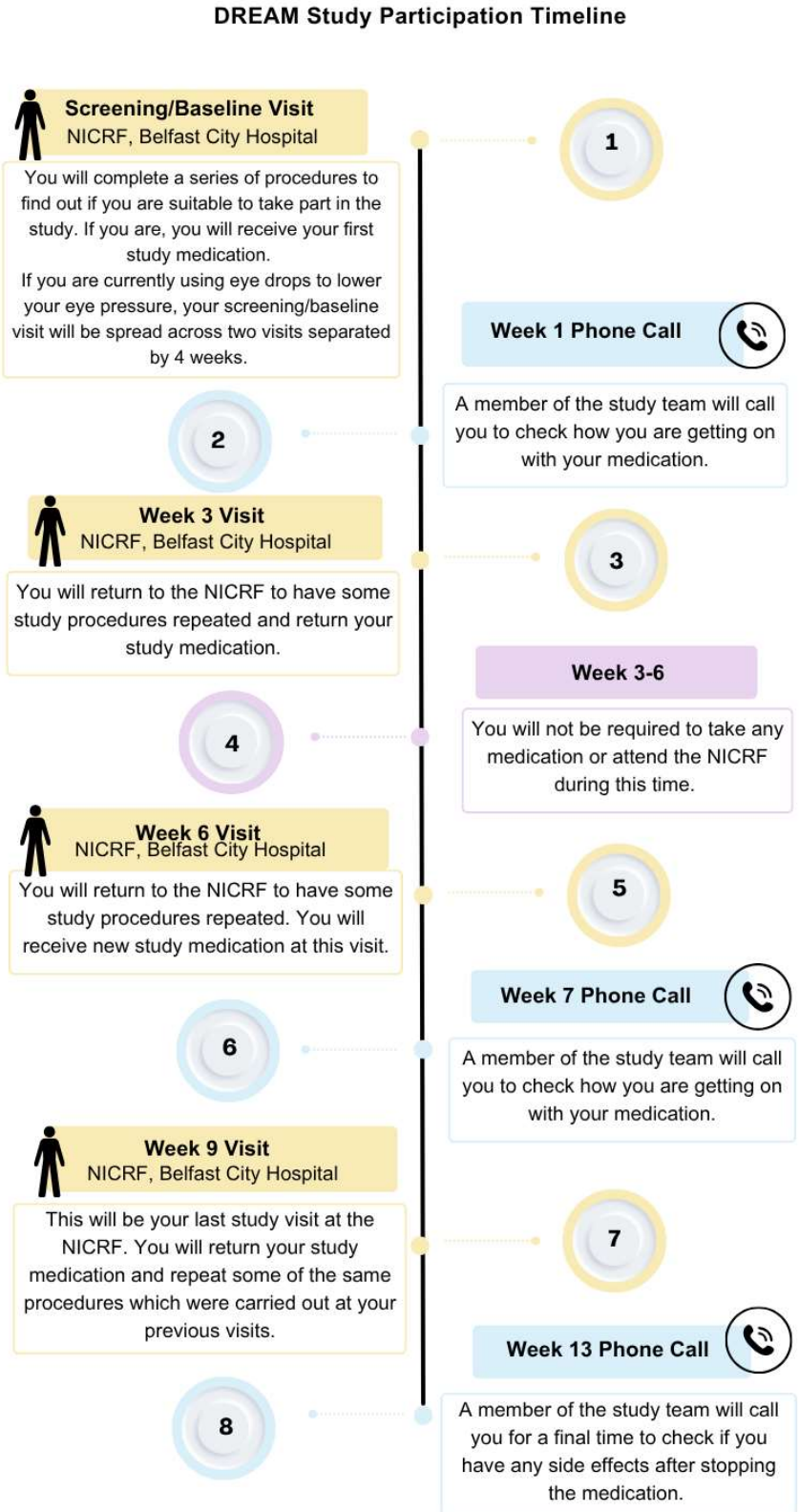
A summary of your participation is included in the flow diagram below:



What happens when my involvement in this research study stops?

If you previously used eye drops before starting the study, you will be asked to start using them again when the study ends. You will continue to be looked after by your normal eye care practitioner either in the hospital or community optometrists.

What are the possible benefits of taking part?

The study aims to assess whether ART27.13, is safe and reduces eye pressure in patients with high eye pressure (ocular hypertension) or glaucoma.

There is no guarantee you will directly receive added benefits from the treatment you receive in this study. We are trying to find out the best treatment for future patients who have high eye pressure (ocular hypertension) or glaucoma.

What are the possible disadvantages and risks of taking part?

If you were already on an eye pressure lowering medication, this will be stopped while you are taking part in the study. However, if your eye pressure becomes too high, the study medication will be stopped and you will restart your previous medication.

The medication used in this study has been used in previous studies and has been well tolerated by patients, with no severe side effects reported. We do not expect any severe side effects to happen in this study, however there could be risks associated that we do not know of yet. The most common side-effects are:

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. You ***should not*** drive or operate heavy machinery in the first 4 weeks each time you start taking the medication. This includes weeks 1 to 4 then again weeks 7 to 10.

For some people, cannabinoids can cause psychiatric reactions. We will use questionnaires to monitor any changes to your feeling and mood throughout the study. In the unlikely event that we notice any changes that require further investigation, we will direct you to the appropriate support services.

You should report all side effects to the study team. If you are having side effects, additional visits may be required to assess, monitor and treat these until they are resolved.

For male participants, your partner should avoid becoming pregnant while you are on the study as there may be a risk to the unborn child. You should wear a condom while on study drug and for 1 month after taking the last dose of the study drug.

If your partner becomes pregnant whilst you are on the study, you must inform the study team immediately and the study medication will be stopped.

If as the study progresses, new safety findings are discovered, you will be informed of these by the study team.

In addition to the potential side effects of the study medication, some of the procedures carried out at your study visits may also pose a small risk.

Blood sampling: You may experience mild pain, bruising or bleeding at the site where the blood sample is taken. You may

also feel dizzy or faint when the sample is being taken. The study team will make every effort to minimise any possible side effects.

ECG: The ECG involves placing sticky patches on the skin. The skin may become red or irritated if you have a response to the sticky material (adhesive) used.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time without giving a reason, and your care will not be affected. If you decide to withdraw from the DREAM study, you should contact the study team (contact details below). If you withdraw from the study, we will use the data collected up to the time you were withdrawn from the study.

Who is organising and funding the study?

The DREAM study is being organised by a group of clinicians and led by Professor Augusto Azuara-Blanco who is an honorary consultant ophthalmologist at the Belfast Health & Social Care Trust and a Clinical Professor at Queen's University Belfast. The Sponsor of the study is the Belfast Health and Social Care Trust (BHSCT). The study Sponsor makes sure the research is conducted to a high standard to safeguard patient safety and data. The Trial Co-ordinating Centre is the Northern Ireland Clinical Trials Unit (NICTU), Belfast Health and Social Care Trust. The study medication is being supplied by Artelo Biosciences. The DREAM study is funded by Glaucoma UK and the Public Health Agency (PHA), Health and Social Care (HSC) Research & Development Division, Northern Ireland.

Who has reviewed the study?

This research has been reviewed and given a favourable opinion by an independent group of people, called a Research Ethics Committee (REC), to protect your safety, rights, well-being, and dignity. The Ethics Committee is completely independent from

the study team. The study has also been reviewed by the regulatory body, the Medicines and Healthcare Products Regulatory Agency (MHRA). Your local NHS trust has given approval for the study to take place at your hospital.

What happens if I have any questions, concerns or complaints about the study?

You should contact the local Principal Investigator or a member of the study team at your hospital (contact details below). They will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the normal health service Complaints Procedure.

What if something goes wrong?

Every effort will be made to ensure that no patient taking part in the study is put at risk or harmed in any way. In the unlikely event that something does go wrong, and you suffer harm as a result, you may have grounds for legal action against the Sponsor (BHSCT) or Queen's University Belfast, but you may have to pay your legal costs.

Will information from the study be kept confidential?

Any personal information which is collected about you during the course of the study will be kept strictly confidential and will only be seen by the study team at the BHSCT, the Trial Co-ordinating Centre, the Sponsor, and people from regulatory authorities who ensure that studies such as this are carried out correctly. All of them will have a duty of confidentiality to you as a research participant.

Because we will need to contact you during the study, the study team at the BHSCT will need to keep a record of your name, address, and other contact details such as telephone number and email address. You have the right to see your personal

health information related to the research study, but you will not be able to review some parts of the information until after the study has finished. Blood samples (for routine tests) will be analysed by the hospital laboratory.

Artelo Biosciences who are supplying the study medication will receive anonymised data to meet regulatory and safety reporting requirements. Anonymised means all personal identifiers will be removed and it will not be possible to identify any individual. The data from this study will be retained for a maximum of twenty-five years after its conclusion at the BHSCT, including the Trial Co-ordinating Centre, and Artelo Biosciences to meet regulatory requirements. The data may be shared with both NHS organisations and Non-NHS Organisations and used in other research studies, including commercial research. If it is used in this way all personal identifiers will be removed, and it will not be possible to identify any individual.

What will happen to the results of the research study?

Recruitment will commence in 2026 and the study is expected to take 1 year to complete. It is envisaged that publication of the results will follow shortly after this, through medical journals, websites, and via appropriate support groups. The results will also be presented to other doctors and nurses at meetings and conferences. Names of participants will not appear in any reports or publications arising from the study. If you would like to receive the study results, please let the study team at your hospital know and provide them with your contact details.

Will my GP be informed of my participation in the study?

Your GP will be notified by letter about your participation in the DREAM study. There may also be instances where GPs will be contacted to follow up incidental findings that may be of clinical significance, such as abnormal ECG. If the GP feels any action

is to be taken based on the information they are provided, they will contact you for a follow-up appointment.

How long can I think about joining the study?

You can take as much time as you need to decide whether you want to take part in the study. Once you receive this information to read and consider, a member of the study team will typically contact you in one week to answer any questions you may have. If you decide to participate, a screening/baseline appointment will be arranged for you at the Belfast City Hospital to obtain your consent and confirm that you are eligible for the study.

Thank you for taking the time to read the DREAM Participant Information Sheet

Contact Details

For any questions about the study, you may contact the research team during work hours using the contact details below:

Principal Investigator: *Update with local details*
Name: «name»
Address: «address»
Telephone: «telephone»

Complaints/concerns: *Update with details for local complaints department and/or Patient Advice and Liaison Service.*
Name: «name»
Address: «address»
Telephone: «telephone»

Chief Investigator:
Name: Professor Augusto Azuara-Blanco
Address: «address»
Telephone: «telephone»

DREAM Trial Co-ordinating Centre:
Address: «address»
Telephone: «telephone»
Email: «telephone

Transparency Statement

How will we use information about you?

We will need to use information from you and from your medical records for this research project. This information will include your name/initials/contact details/date of birth/ethnicity/HSC Number. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or your contact details. Your data will have a code number instead.

Belfast Health and Social Care Trust (BHSCT) is the sponsor of this research. BHSCT is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Academic institutions
- Commercial companies (Artelo Biosciences)

We will keep all information about you safe and secure by:

- Complying with data protection laws and standards (e.g., General Data Protection Regulations (GDPR)
- Restricting access to personal data to authorised personnel only
- Ensuring all staff receive regular training on data protection and security best practices
- Implementing firewalls, antivirus software and regular security patches to protect systems

- Regularly monitoring and auditing our systems for security vulnerabilities

International Transfers?

We may share or provide access to data about you outside the UK for research related purposes to:

- Allow Artelo Biosciences to meet their regulatory requirements.
- Assist other health organisations, academic institutes or commercial companies in future research studies.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Other health organisations
- Academic institutions
- Commercial companies

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data

against accidental loss and unauthorised access, use, changes or sharing.

- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 25 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study.
- You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
- If you agree to take part in this study, you will have the option to take part in future research using the data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- by asking one of the study team
- by sending an email to the DREAM research team: DREAM@nictu.hscni.net
- by ringing us on [phone number]
- www.belfasttrust.hscni.net/about/access-to-information/data-protection/
- www.hra.nhs.uk/patientdataandresearch