Patient Information Sheet

PARAGON; PAtient Reported outcomes After Greater Occipital Nerve block

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Who is carrying out the study and why?

The Chief Investigator for this study is Dr Jitka Vanderpol, Consultant Neurologist. This study has been developed by NHS staff and is carried out in Cumbria Partnership NHS Foundation Trust, Hull and East Yorkshire Hospitals NHS Trust, City Hospitals NHS Sunderland Foundation Trust, and Newcastle upon Tyne Hospitals NHS Foundation Trust. The lead investigator at your local NHS Trust is [name of consultant]. The study will take place in an outpatient setting with support and oversight from the treating neurologist, nursing and research staff.

The aim of this study is to determine if the way a patient is positioned shortly after a GON (greater occipital nerve) block affects the effectiveness of the actual GON block treatment. There will be no change in the GON block treatment itself, only in how the patient is positioned in the recovery period for 10 minutes after the GON block procedure.

Another objective of the study is to determine if the use of an app by patients to record headaches is a suitable alternative to using paper headache diaries.

Why have I been invited?

You are being asked to participate in this research study because your clinical team have identified you as someone who has a primary headache disorder who qualifies for GON block treatment with the aim to alleviate your headache symptoms.

Do I have to take part?

You do not have to take part; it is entirely up to you to decide whether you would like to be involved in our study. Take your time, discuss things with others and ask us about anything that is not clear or if you would like more information. Regardless of whether you decide to take part or not, your clinical treatment will not be affected by your decision. You are free to withdraw at any time without explanation and this will not affect the standard of care you receive in any way. If you withdraw at any stage of the study, then we will retain any study information collated up to that point.

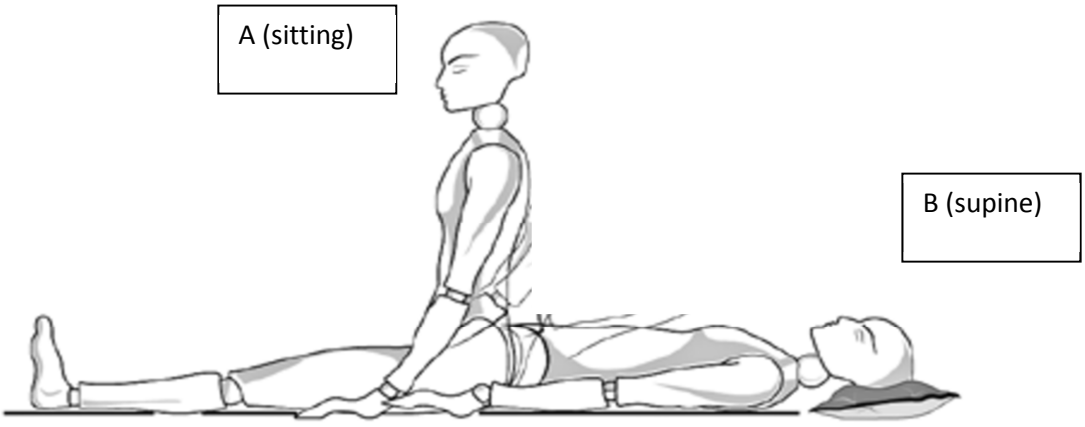
What will happen to me if I take part?

If you decide that you may want to take part in the study, one of the research staff, which may be the local investigator or a trained and delegated member of the study team, will take written consent from you. We ask permission to access your medical records to record data related to your headache and treatment. We also ask permission to inform your GP of your participation in the study.

The trial intervention is how a patient is positioned straight after the GON block, for 10 minutes (see Figure 1). On the day of your GON block appointment you will be allocated to either the **sitting group** (sitting position post GON block) or the **supine group** (lying position).

- **Sitting group**: you will receive current standard care; the GON block and then remain seated in a sitting position for 10 minutes after the procedure.
- **Supine group**: you will receive the GON block and then assume a lying position for 10 minutes.

Figure 1. Sitting up position vs Lying down (supine) position following GON block procedure



You will first be approached about the study during your clinic visit with the neurologist where you also discuss whether you are suitable for receiving GON block. If indeed you are listed for GON block a few more checks will be made to see if you are eligible to take part in the PARAGON study. For example, one requirement is that you have access to a smartphone, computer or tablet to use an app to record your headaches. This App has been developed by a company called Curelator (https://curelator.com/). When in the study you are asked to use the app daily to record: any headache(s) experienced, and if so what the characteristics of the headache were (length, intensity, etc).

Once written informed consent has been obtained from you, we will record a few baseline items, such as you age, sex, height, weight, and some information about your headache disorder diagnosis. We will also ask you to complete up to three questionnaires related to your headache disorder and how it impacts on your daily living (HIT-6, MIDAS and MSQ for migraine patients).

At your next appointment for your GON block, you will be randomised to one of two patient positions and we will ask you how painful you thought the GON block procedure was. Please note that you will only be randomised if you have completed the Curelator App daily on at least 80% of days in a 30 days period running up to the GON block appointment.

During the follow-up period we will ask you to complete the same questionnaires as before at 30 and 90 days after the GON block appointment. In addition we will ask you about the relief you have had from the GON block procedure and what you think of the Curelator app. As mentioned, this can be done remotely and you can complete these questionnaires from the comfort of your own home.

Table 1 summarises what happens at each study time point. Study participants do not have to visit the neurology clinic more often than normal. All follow-up visits can be done remotely, via e-mail, phone or post. If you do wish to visit in person for the follow-up appointments then that can be arranged.

Table 1, Timeline and overview of different study visits

Type of visit	**Point of contact (where)**	**What will happen?**
Baseline (up to 90 days before GON block) visit	Neurologist and researcher (clinic)	• Screening for trial eligibility • Written Informed Consent • Info on type of headache, height/weight etc • Questionnaires (HIT6, MIDAS, MSQ) • Complete Curelator App – daily for 30 days
GON block procedure visit	Neurologist (clinic)	• Randomisation to one of two groups • Patient position after GON block, 10 min. • Pain scale questionnaire after GON block
Follow-up visit 1 (30 days after GON block)	Researcher (e-mail / phone / post)	• Headache RELIEF questionnaire • Questionnaires (HIT6, MIDAS, MSQ) • Complete Curelator App – daily for 30 days
Follow-up visit 2 (90 days after GON block)	Researcher (e-mail / phone/ post)	• Headache RELIEF questionnaire • Questionnaires (HIT6, MIDAS, MSQ) • Complete Curelator App – daily for another 60 days • Patient experience questionnaire

What are the possible benefits of taking part?

This study looks to find out if one patient position is more effective than the other in minimising headache-related pain (frequency, intensity etc). At the moment there is some indication that one position is better than the other. However, this has not yet been proven

and established, and this study is aimed to assess this. As part of this trial we will also assess if the use of a headache-recording app is useful to check a patient's headache frequency. The Curelator headache app will be provided to participants free of charge and normally retails at approximately £48.

You cannot claim payments, reimbursement of expenses or any other benefits or incentives for taking part in this research.

What are the possible disadvantages and risks of taking part?

There is no personal safety risk anticipated regarding taking part in this study. There is no risk anticipated with sitting up or lying down for 10 minutes after the GON block procedure. Like with any invasive procedure, the GON block procedure itself (which is not classed as a trial intervention) carries risks such as localised bleeding and localised hair loss.

If you do decide to take part in the PARAGON study, and your Neurologist, nurse or the research team learns of important new information that might affect your desire to remain in the study, they will tell you as soon as possible. Appropriate precautions are in place to ensure your medical and personal information is kept safe (see next sections).

What will happen to the information that I give?

All data will be held in secure environments in NHS Trusts. The requirements of the Data Protection Act and NHS Code of Confidentiality will be followed at all times. All researchers will be fully trained in NHS Confidentiality. Data released (e.g. by publication) will be anonymous; it will not contain any information that could lead to the identification of an individual participant. As part of providing a research grant for this study, we will share *anonymised* research data with Curelator Inc company (the manufacturer of the Curelator App), for which we will ask your written consent. Any information that you enter onto the Curelator App will be processed and stored in line with applicable laws and regulations – it will not be shared with third parties.

Will my participation in the study be kept confidential?

All your personal details will be treated as STRICTLY CONFIDENTIAL, in line with the Data Protection Act. Your data collected during your participation will be entered into a password-protected database and analysed – using only NHS computers and servers. None of your study data will be identified by your name – only by study number. Appropriate measures will be enforced to protect your identity in all presentations and publications, as required by United Kingdom regulations. The Sponsor's clinical research staff, consultants, one or more nominated research organisation(s) working on behalf of Sponsor, Sponsor's auditors or their representatives, the NHS representatives and regulatory authorities may

have direct access to your medical records in order to make sure that the study is conducted correctly and to verify the results of the study. You authorise such direct access to your medical records by signing the informed consent form.

Cumbria Partnership NHS Foundation Trust (CPFT) is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. CPFT will keep identifiable information about you for 15 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at https://www.cumbriapartnership.nhs.uk/the-trust/access-to-records/how-the-trust-manages-your-information or by contacting research@cumbria.nhs.uk.

[name of participating Trust] will use your name, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from CPFT and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

What if something goes wrong?

If you have any concerns at any stage of your involvement in this research project, please feel free to discuss these with the research team. We will do our best to resolve any problems quickly. If you are still unhappy and wish to complain about any aspect of the way you have been approached, the normal National Health Service (NHS) complaints mechanisms are available to you (Patient Experience Team contact details below).

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

Your participation in the study is voluntary. You can refuse to take part, or you can withdraw at any time. If you choose to withdraw, your clinician will continue treating you as he or she normally would and you do not have to give a reason as to why you wish to withdraw from the study. If you withdraw after signing the study consent form, you will not be able to re-enter the study. Any data collected up to the point where you withdraw will be retained for analysis as part of the study. The latter also applies if you were to lose capacity to take part during the study.

Who is organising and funding the study?

The study is organised by Consultant Neurologist Dr Jitka Vanderpol in collaboration with the Research Department of Cumbria Partnership NHS Foundation Trust. This NHS Trust is also the study sponsor for indemnity purposes. The study has been reviewed and approved by the National Ethics Research Service, South Central Oxford A REC committee, REC ref 18/SC/0334, the Health Research Authority and the NHS Trusts where the study is conducted. The Curelator Inc Company is funding this study by means of an academic research grant.

The research team acts as a contact point and coordinator for patients requiring information and support. If concerns are raised, referral of patients/families on to other professional agencies will be done as appropriate and according to the Trust guideline.

Contact for further information

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from the PARAGON research team:

- Name: Charlotte Halliday (Research Practitioner), Ms Emma Mark (Research Nurse), and Dr Jitka Vanderpol (Consultant Neurologist)
- Phone number: 01228 602173
- Email: Research@cumbria.nhs.uk

Generic information on taking part in clinical research can be obtained from the Patient Experience Team, tel 0800 633 5547 or PET@cumbria.nhs.uk , or from websites such as the NHS Choices website, http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Thank you for taking the time to read this information sheet