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Patient reported outcomes after GON block

Submission date
03/09/2018

Recruitment status
No longer recruiting

Registration date
04/09/2018

Overall study status
Completed

Last Edited
14/04/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Primary headache disorders, including migraine, cluster headache, and occipital neuralgia, are some of the most debilitating conditions that impact negatively on patients themselves and the wider economy. Some patients do not respond to currently available prophylaxis (preventative) and rescue medication. Nerve block medication treatment is offered to these treatment-resistant patients. Greater occipital nerve (GON) block is an established nerve block procedure that has a favourable safety profile and is cost-effective – the active ingredients used are a mix of local anaesthetic agent and steroid. The exact effectiveness and the best method for delivering GON block is not yet known due to a relative lack of evidence from gold-standard randomised controlled trials and variety in the applied GON block procedure. Initial pilot data on GON block patients, and related evidence from use of anaesthetics in dentistry, suggests that lying a patient down for ten minutes after the procedure enhances the effectiveness of the GON block and thereby leads to an increase in the achieved headache-free period. This present study seeks to determine whether the patient's position straight after injection of the GON block medicine influences headache symptoms afterwards. A headache-reporting App called Curelator, used by participating patients during the trial, may reduce the bias observed with retrospective patient recall of headache episodes.

Who can participate?
Patients aged 18 or older with primary headache disorder

What does the study involve?
Participants 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). They use the app for a total of 120 days (30 days before GON block, and up 90 days after the GON block). Participants complete up to three questionnaires related to headache disorder and how it impacts on their daily living. At their next appointment for their GON block, they are randomly allocated to one of two patient positions (sitting or lying down) and are asked how painful they thought the GON block procedure was. During the follow-up period the participants are asked to complete the same questionnaires as before at 30 and 90 days after the GON block appointment. In addition they are asked about the relief they have had from the GON block procedure and what they think of the Curelator app. 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.

What are the possible benefits and risks of participating?
This study aims 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. This trial 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 about £48. Participants cannot claim payments, reimbursement of expenses or any other benefits or incentives for taking part in this study. 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 patients decide to take part in the study, and their Neurologist, nurse or the research team learns of important new information that might affect their desire to remain in the study, they will tell the participants as soon as possible. Appropriate precautions are in place to ensure participants' medical and personal information is kept safe.

Where is the study run from?
1. Cumbria Partnership NHS Foundation Trust (UK)
2. City Hospitals NHS Sunderland Foundation Trust (UK)
3. Hull and East Yorkshire Hospitals NHS Trust (UK)
4. Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2018 to March 2021

Who is funding the study?
Curelator, Inc.

Who is the main contact?
Dr Leon Jonker
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38836

Study information

Scientific Title
The effect of patient positioning on patient reported outcomes after GON block for primary headache disorder: a multi-centre, four-arm, controlled, prospective randomised trial

Acronym
PARAGON

Study objectives
This study seeks to use a prospective, randomised, multi-centre approach to determine whether the patient's position straight after injection of GON block influences the patient-reported outcomes regarding headache symptoms afterwards. A headache-reporting App called Curelator, used by participating patients during the trial period, will allow prospective recording of headaches which may reduce the bias observed with retrospective patient recall of headache episodes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford A Research Ethics Committee, 19/06/2018, ref: 18/SC/0334

Study design
Randomised; Interventional; Design type: Treatment, Physical

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Headache disorder, including migraine, occipital neuralgia, cluster headache and trigeminal autonomic cephalgia

Interventions
The patient will first be approached about the study during their clinic visit with the neurologist where it will also be discussed whether the patient is suitable for receiving GON block. If indeed they are listed for GON block a few more checks will be made to see if they are eligible to take part in the PARAGON study. For example, one requirement is that they have access to a smartphone, computer or tablet to use an app to record their headaches.

When in the study they 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). Therefore, they will use the App for a total of 120 days max (30 days before GON block, and up 90 days post-GON block).

Once written informed consent has been obtained from the patient, they will be asked about a few baseline items, such as age, sex, height, weight, and some information about their headache disorder diagnosis. They will also be asked to complete up to three questionnaires related to headache disorder and how it impacts on their daily living (HIT-6, MIDAS and MSQ; the latter for migraine patients only).

At their next appointment for their GON block, participants will be given single treatment unilateral or bilateral GON block, inserting a 22-23 gauge needle, using dose of Lidocaine 2% (20mg) with Depo-Medrone (80mg) in 2 ml vial, injected close to GON output (1/3 of distance between external protuberance and mastoid process). The intervention is as follows: directly following conclusion of the GON block procedure the patient will either:
A. Remain seated vertical (sitting)
B. Lie horizontally in a supine position for 10 minutes (with head rested on pillow at approximately 30 degree angle), measured with stopwatch

Please note that they will only be randomised if they have completed the Curelator App daily on at least 90% of days in a 30 days period running up to the GON block appointment.

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

Below is a summary of 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.

Baseline (up to 90 days before GON block) visit with Neurologist and researcher in 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 with Neurologist in 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) with Researcher via 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) with Researcher via e-mail/phone/post:
• Headache RELIEF questionnaire
• Questionnaires (HIT6, MIDAS, MSQ)
• Complete Curelator App – daily for another 60 days
• Patient experience questionnaire

Intervention Type
Procedure/Surgery

Primary outcome measure
RELIEF (headache relief) patient-reported outcome score at 90 days post-GON block; the score will also be recorded at 30 days post-GON block

Secondary outcome measures
1. Headache-free period post-GON block in days (up to 90 days post-GON block)
2. Average monthly headache days (in 30 days before GON block and up to 90 days post-GON block)
3. Severity of headache (severe, moderate, mild, none; (in 30 days before GON block and 30/90 days post-GON block)
4. Headache characteristics (in 30 days before GON block and 30/90 days post-GON block), including aura, photophobia
5. Average length of each headache episode in hours (in 30 days before GON block and 30/90 days post-GON block)
6. Impact of headache disorder on quality of life (in 30 days before GON block and 30/90 days post-GON block) using HIT-6, modified MIDAS, MSQ validated questionnaires (latter for migraineurs only)
7. Prophylactic and/or rescue medication use: total cost of medicine use (in 30 days before GON block and 30/90 days post-GON block), using British National Formulary as source for costs
8. Adverse event reporting by participants (at 30 days post-GON block)

Overall study start date
30/08/2018

Completion date

31/03/2021

Eligibility

Key inclusion criteria
1. Diagnosis fulfilling IHS criteria for primary headache disorder, which includes:
2. For migraine cohort:
2.1. Episodic or chronic migraine
3. For non-migraine cohort:
3.1. Occipital neuralgia
3.2. Cluster headache
3.3. Trigeminal autonomic cephalgia (TAC)
3.4. Non-specified or other primary headache disorder
4. Deemed eligible for GON block procedure as determined by treating neurology team
5. Aged 18 or older
6. Mental capacity to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 84; UK Sample Size: 84

Total final enrolment
172

Key exclusion criteria
1. Under the age of 18 years
2. Unable to fully understand the consent process and provide informed consent due to either language barriers or mental capacity
3. Any condition that precludes patients from receiving GON block, including:
3.1. Disorders associated with excessive bleeding, coagulation abnormalities or any other significant haematological condition (e.g. Factor V Leiden, haemophilia, thrombocytopaenia).
3.2. Known acute or previous base of skull fracture
3.3. Allergy or hypersensitivity to any active ingredients or excipients used for GON block
4. Patients who are participating in another interventional research study involving an investigational product related to their headache disorder
5. The patient has concurrent (medical) conditions that in the opinion of the investigator may compromise patient safety or study objectives
6. Subjects who have received greater occipital nerve blocks (both GON or Botox) in the last 6 months, or are still headache-free following an intervention

7. For randomisation after baseline period:
7.1. Less than two headache episodes in baseline 30 day data collection period
7.2. Curelator App used < 90% of 30 day baseline diary period

Date of first enrolment
10/09/2018

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cumbria Partnership NHS Foundation Trust
Neurology Department
Penrith
United Kingdom
CA11 8JA

Study participating centre
City Hospitals NHS Sunderland Foundation Trust
Neurology Department
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United Kingdom
SR4 7TP

Study participating centre
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United Kingdom
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Study participating centre
Newcastle upon Tyne Hospitals NHS Foundation Trust
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NE1 4LP

Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
Curelator, Inc.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/09/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2	23/08/2018	04/09/2018	No	Yes
Protocol file	version v2	23/08/2018	04/09/2018	No	No
Protocol file	version v4	26/02/2019	12/07/2019	No	No
Protocol file	version V6	04/02/2020	21/09/2020	No	No
Plain English results		14/04/2022	14/04/2022	No	Yes
HRA research summary			28/06/2023	No	No