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Blocking of the Sphenopalatine ganglion (nerve cells located behind the nose) is an effective treatment for acute migraine headaches

Submission date
18/12/2017

Recruitment status
No longer recruiting

Registration date
08/01/2018

Overall study status
Completed

Last Edited
11/02/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The sphenopalatine ganglion is a collection of nerve cells located behind the nose on each side of the face. Due to its complex connections to important structures in the head and meninges (brain coverings), it plays an important role in migraine headaches and other headache and facial pain conditions, such as cluster headache. Injecting certain medications into this structure helps relieve migraine headaches as well as its associated symptoms, such as tearing, runny nose and light sensitivity. The treatment is done using simple safe devices (called catheters) inserted through the nose, using lidocaine solution (which is used in the dentist office for numbing the gum). The treatment is simple and safe with effect that may last for days or longer, and can be repeated at regular intervals to help reduce migraine attack severity and frequency. The aim of this study is to treat patients who are known to have migraine and present with an acute attack not responding to usual pain medications.

Who can participate?
Adults aged 18 to 60 years old who have migraine headaches.

What does the study involve?
Participants have a numbering medication called lidocaine injected using the SPHENOCATH, which is a small soft tube. The medicine is injected while the patient is lying down and is directed at a group of nerve cells called the sphenopalatine ganglion, located behind the nose on each side. Participants are asked to remain lying down on their back of 10 minutes in order to ensure that the medicine reached the proper place.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement in their headache symptoms. The procedure is very safe and well-tolerated, with few side effects, such as numbness of the throat (usually lasting less than 30 minutes), mild nausea and mild dizziness that go away in few minutes. The procedure can safely repeated every 2-4 weeks as needed, and the treatment effect usually lasts few days to few weeks.

Where is the study run from?
University Medical Center, King Abdullah Medical City (Bahrain)

When is the study starting and how long is it expected to run for?
February 2017 to October 2017

Who is funding the study?
University Medical Center, King Abdullah Medical City (Bahrain)

Who is the main contact?
Dr Mohamed Albinfalah (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Mohamed Albinfalah

Contact details
University Medical Center, King Abdullah Medical City
PO Box 26671
Manama
Bahrain
109

Additional identifiers

Protocol serial number
70809

Study information

Scientific Title
Sphenopalatine ganglion block for the treatment of acute migraine headache

Study objectives
Although there are currently many options for acute migraine treatment, such as acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDS), triptans, combinations analgesics, and anti-emetics, these treatment options are often suboptimal, with inadequate efficacy and significant side effects. In addition, several studies have shown that migraine patients with poor response to acute treatment are at increased risk for transformation to chronic migraine (CM), with roughly 2.5-3.5-fold greater odds of developing CM; patients with a moderate or better acute treatment efficacy did not have a significant increased risk. Therefore, there is a continuous need for new treatment modalities to address the therapeutic needs of migraine sufferers, especially those with frequent and disabling attacks.

Sphenopalatine ganglion (SPG) block has gained interest as an effective treatment modality for migraine and other headache and facial pain syndromes. The SPG, which is the major

parasympathetic outflow to the cranial and facial structures, is a reasonable target to help relief pain and autonomic features seen in migraine and other headache and facial pain conditions such as cluster headache and trigeminal neuralgia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of University Medical Center at King Abdullah Medical City, 20/02 /2017

Study design
Open uncontrolled retrospective study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute migraine headache

Interventions
Prior to procedure, the nose is inspected for any obstruction, and xylometazoline 0.05% nasal drops (one drop in each nostril) are used to help open the nasal passages. Face temperature is recorded using temperature sensor skin probes put on both cheeks. A small amount of 2% lidocaine jelly is installed in each nostril for patients' comfort, using a needless syringe. Each patient received a single treatment of transnasal SPG block with 2 cc of 2% lidocaine in each nostril in the supine position with head extension, delivered using the Sphenocath® device. This is a small flexible sheath with a curved tip. It is inserted through the anterior nasal passage parallel to nasal septum and above the middle turbinate. Once in place, the inner catheter is advanced to administer 2cc of 2% lidocaine. It is then removed and the procedure is repeated on the other side. Typically after the block, there is an increase in face temperature by 1 to 2 degrees Celsius and/or tearing. The patient is instructed to remain in the same position for 10 minutes. Pain is assessed using numeric rating scale (NRS), where 0 is no pain and 10 is worst pain imaginable; this was recorded at baseline, 15 minutes, 2 hours and 24 hours after the procedure. We also recorded patient global impression of change (PGIC; very poor, poor, no change, good, very good) at 2 hours and 24 hours post-procedure.

Intervention Type
Device

Primary outcome(s)
1. Percentage of patients free of headache using the numeric rating scale at 15 minutes, 2 hours and 24 hours
2. Pain is assessed using the numeric rating scale (NRS) at baseline, 15 minutes, 2 hours and 24 hours after the procedure

Key secondary outcome(s))

1. Headache relief rate, defined as percentage of patients with 50% or more reduction in headache intensity is measured using the numeric rating scale (NRS) at 15 minutes, 2 hours and 24 hours (using the NRS)
2. Change in NRS from baseline to 15 minutes, 2 hours and 24 hours post-treatment
3. Patient global impression of change (on a scale: very poor, poor, no change, good, very good), measuring effects on headache and its associated symptoms, and tolerability) at 2 hours and 24 hours
4. All adverse events reported by the patients up to 24 hours post-procedure

Completion date
31/10/2017

Eligibility

Key inclusion criteria
1. Aged between 18 to 60 years of age
2. Diagnosed with migraine headache (according to International Classification of Headache Disorders-3 Beta since at least one year)
3. Present with moderate to severe headache not responding to abortive medications

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
55

Key exclusion criteria
1. Patients with medication overuse headache
2. Bleeding disorders
3. Abnormal neurological examination
4. History of allergy to local anesthetics

Date of first enrolment
01/03/2017

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
Bahrain

Study participating centre
University Medical Center, King Abdullah Medical City
Manama
Bahrain
26671

Sponsor information

Organisation
University Medical Center, King Abdullah Medical City

ROR
https://ror.org/054atdn20

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Center, King Abdullah Medical City

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Mohamed Albinfalah (mfalahmd@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/05/2018	11/02/2022	Yes	No