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Vidian neurectomy for management of chronic cluster headache

Submission date
25/04/2017

Recruitment status
No longer recruiting

Registration date
23/05/2017

Overall study status
Completed

Last Edited
23/05/2017

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Cluster headaches are a type of headache which involves excruciating attacks of pain on one side of the head. They can affect people of any age, but tend to be more common in men and people over the age of 20. Attacks can be described as stabbing and of the most severe intensity “like a knife penetrating behind the eye”. Cluster headaches can be difficult to treat with 15-20% of patients not responding to drug treatment. The severity of pain and the frequency of attacks seriously degrade patients’ quality of life, justifying the consideration of other, more drastic therapies. Trans-nasal endoscopic vidian neurectomy is a surgical technique is a surgical technique which involves severing or removing the vidian nerve (a nerve in the head). The aim of this study is to find out whether this procedure is an effective treatment for long-term (chronic) cluster headaches.

Who can participate?
Adults who have been suffering from daily cluster headaches for three years.

What does the study involve?
All participants undergo a trans-nasal endoscopic vidian neurectomy while under general anesthesia (put to sleep). After this procedure, most patients can leave the hospital at the same day and without other discomforts except a feeling of fullness in the nose. At the start of the study and then one week and one, three and six months after the surgery, patients are interviewed and complete a questionnaire to find out if their symptoms have improved.

What are the possible benefits and risks of participating?
Participants nay benefit from an improvement to their cluster headache symtpoms. There is a risk of developing dry eyes, a dry nose or numbness in the palate (roof of the mouth).

Where is the study run from?
Taipei Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation (Taiwan)

When is the study starting and how long is it expected to run for?
August 2011 to December 2016

Who is funding the study?
Investigator initiated and funded (Taiwan)

Who is the main contact?
Dr Shao-Cheng Liu
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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
20170425-VN

Study information

Scientific Title
Surgical role of vidian neurectomy in treating chronic cluster headache

Study objectives
Precise vidian neurectomy (VN) with maximal preservation of SPG activity is both effective and safe in patients with chronic cluster headache with failed pharmacological management.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Buddhist Tzu Chi General Hospital-Taipei Branch

Study design
Single-centre non randomised interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic cluster headache

Interventions
All participants undergo a trans-nasal endoscopic vidian neurectomy with maximal preservation of spheno-palatine ganglion activity. This involves precisely nerve transect via an endoscopic trans-naasl approach and no cauterization was used over the distal stump of the vidian nerve to avoid thermal injury of spheno-palatine ganglion.

At baseline, one week, and one, three, six and twelve months post procedure, participants undergo a range of assessments to measure the change of their headache pattern, including mean attack frequency, mean attack intensity, and pain disability index, by patient interviews and medical tests.

Intervention Type

Primary outcome measure
Headache pattern is measured by patient interviews, to obtain the change of the mean attack frequency (numbers of attacks per week) and mean attack intensity (using the visual analogue scale (VAS)) at baseline, one week, and one, three, six and twelve months post procedure.

Secondary outcome measures
The degree participants' daily lives disrupted by cluster headache is obtained by patient interviews and questionnaire: the pain disability index (PDI) at baseline, one week, and one, three, six and twelve months post procedure.

Overall study start date
31/08/2011

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Diagnosis of CCH according to the criteria of International Classification of Headache Disorders 2nd edition (ICHD-II)
2. Duration of CH exceeding three years
3. Daily attacks
4. Resistance to more than two pharmacological prophylactic treatments with adequate trials including rizatriptan or other available drugs in Taiwan (verapamil, lithium or steroid)
5. Treatment by vidian neurectomy ranked as a precise cut, with follow-up exceeding one year
6. Aged 17 years and over

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
9

Key exclusion criteria
Patients with cluster headache who show good response to pharmacological treatments.

Date of first enrolment
01/03/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Taiwan

Study participating centre
Taipei Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation
No.289, Jianguo Road
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Sponsor information

Organisation
Taipei Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/037r57b62

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication of study results in a high-impact peer reviewed journal (such as Scientific Reports).

Intention to publish date
31/12/2017

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 Shao-Cheng Liu (m871435@ndmctsgh.edu.tw)

IPD sharing plan summary

Available on request