# A randomised controlled trial of pulsed radiofrequency lesioning of the Gasserian ganglion for trigeminal neuralgia.

Recruitment status	Prospectively registered
Stopped	☐ Protocol
Overall study status	Statistical analysis plan
Stopped	☐ Results
Condition category	Individual participant data
Nervous System Diseases	Record updated in last year
	Stopped  Overall study status Stopped  Condition category

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

N0259149058

# Study information

### Scientific Title

# Study objectives

Does Pulsed Radio frequency (RF) lesioning produce any neurological damage? Standard RF lesioning produces a lesion by electronically heating the tip of the electrode to a controllable temperature between 60 and 90 degrees C to deliberately partially damage the nerve tissue, thus reducing the pain. Pulsed RF is claimed to be an effective way of producing an analgesic effect without damaging the nerve in any way, because the average temperature at the tip of the electrode is 42 degrees. It is claimed that it affects function in an unexplained way, without any neurological damage. Nerve damage can produce numbness with pain persisting, or a further neuropathic pain developing as a result of the nerve damage.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

# Primary study design

Interventional

### Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

### Study type(s)

**Not Specified** 

### Participant information sheet

### Health condition(s) or problem(s) studied

Nervous System Diseases: Neuralgia

#### **Interventions**

Parallel group, patient and assessor blind randomised controlled study. Patients would be checked as to their suitability for the study according to the entry criteria, and then receive a full assessment. Suitable patients would be investigated with an MRTA and a MRI of brain, together with laboratory investigation, neurophysiology and QST. Patients would be stratified as to typical or atypical forms of TGN, and randomised to receive either standard or pulsed RF lesion to the Gasserian Ganglion. Both patients and assessors would be blinded as to the treatment performed. The blinding would be maintained until return of pain, at which time a standard RF lesion or other clinically acceptable treatment such as balloon compression, stereotactic

radiosurgery etc. will be performed. The pulsed or conventional RF lesion will be performed using the Radionics lesion generator. The patient will receive Midazolam sedation in the standard way. The RF needle (RDG Neurotherm cannula) will be positioned in the foramem ovale under X-ray control and the appropriate trigeminal root located with sensory thresholds of less than 0.5v29. A pain diary will be kept, using a pain logger, for the week preceding the RF lesion, together with a diary of interference with activities of daily living. This diary would continue after the procedure for 1 month, and will be re-introduced if pain relief follows the procedure and pain then returns at a later date. Time to return of pain will be noted. The patient will have specific instructions to notify the researchers when pain returns, and will be re-assessed at that time. Formal assessment will be done otherwise at 1-2 week(s), 1 month, 3 months, 6 months, 9 months and 12 months, 18 months and 2 years.

### **Intervention Type**

Other

#### Phase

**Not Specified** 

### Primary outcome measure

Not provided at time of registration

# Secondary outcome measures

Not provided at time of registration

### Overall study start date

01/05/2004

### Completion date

01/05/2008

### Reason abandoned (if study stopped)

Lack of time from trialist. Poor patient recruitment.

# **Eligibility**

### Key inclusion criteria

Patients will be selected who have a diagnosis of trigeminal neuralgia with unilateral pain, failure of acceptable pharmacological control, failure of mirovascular decompression, or patients not otherwise suitable for surgery.

# Participant type(s)

**Patient** 

### Age group

**Not Specified** 

#### Sex

**Not Specified** 

# Target number of participants

Not provided at time of registration

# Key exclusion criteria

Not provided at time of registration

# Date of first enrolment

01/05/2004

### Date of final enrolment

01/05/2008

# Locations

# Countries of recruitment

England

**United Kingdom** 

# Study participating centre

The Walton Centre for Neurology and Neurosurgery Liverpool United Kingdom L9 7LJ

# Sponsor information

# Organisation

Department of Health

# Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

### Sponsor type

Government

# Website

http://www.dh.gov.uk/Home/fs/en

# Funder(s)

# Funder type

Government

### Funder Name

The Walton Centre for Neurology and Neurosurgery NHS Trust (UK)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration