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A randomised controlled trial of pulsed radio-frequency lesioning of the Gasserian ganglion for trigeminal neuralgia.

Submission date 30/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Stopped	
Last Edited 10/04/2008	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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Sponsor information

Organisation
Department of Health

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Richmond House
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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