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Invasive Therapy for Cervicogenic Headache

Submission date 08/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/08/2005	**Overall study status** Completed	
Last Edited 07/01/2021	**Condition category** Signs and Symptoms	

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
N/A

Study information

Scientific Title
Invasive Therapy for Cervicogenic Headache

Acronym
ITCH

Study objectives
A sequence of cervical radiofrequency lesions (directed at the cervical facet joints, eventually followed by dorsal root ganglion lesions) is more effective than conservative therapy (local injections with anaesthetic and methylprednisolone of the greater occipital nerve, eventually followed by transcutaneous nerve stimulation) in alleviating headache in patients with cervicogenic headache

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cervicogenic headache

Interventions
Radiofrequency neurotomy of the cervical facet joint, eventually followed by a radiofrequency lesion of a cervical dorsal root ganglion versus conservative therapy (local injections with anaesthetic and methylprednisolone of the greater occipital nerve, eventually followed by transcutaneous nerve stimulation)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Methylprednisolone

Primary outcome measure
Mean visual analogue scores of pain at 8 weeks, 3-months, 6-months and 1 year

Secondary outcome measures
Global perceived effect by patient at the above-mentioned timepoints. The number of headache days, the medicine use and the headache intensity during a week were also recorded.

Overall study start date
01/09/1997

Completion date
01/07/2002

Eligibility

Key inclusion criteria
The study group was recruited from patients with cervicogenic headache (CH) according to the diagnostic criteria of Sjaastad. The other following inclusion criteria had to be fulfilled:
1. Age between 20 and 65 years; chronic cervicogenic headache of more than 2 years' duration
2. An initial visual analogue scale (VAS) score of more than 50 mm during a pain period
3. A significant pain during at least two days per week
4. At least one of the following symptoms on physical examination of the neck: paravertebral tenderness on palpation of the cervical spine and/or positive tender points at specific points indicating the involvement of segmental nerves and/or reduction of range of motion in the cervical spine

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
Excluded from the study were patients who had previous surgical procedures of the cervical spine; who had coagulation disturbances; who were pregnant; who had multilevel severe degenerative changes; who were diagnosed with post-whiplash syndrome and in whom none of the symptoms on physical examination described above were present.

Date of first enrolment
01/09/1997

Date of final enrolment
01/07/2002

Locations

Countries of recruitment
Netherlands

Study participating centre
Dept. Neurology
Maastricht
Netherlands
6202 AZ

Sponsor information

Organisation
University Hospital Maastricht, Pain Centre (The Netherlands)

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Sponsor type
University/education

Website
http://www.pijn.com

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
University/education

Funder Name
University Hospital Maastricht, Pain Centre (Netherlands)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/02/2006		Yes	No