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A randomised, double-blind, placebo controlled, cross-over trial with low dose amitriptyline in the management of midfacial segment pain

Submission date
30/09/2005

Recruitment status
Stopped

Registration date
30/09/2005

Overall study status
Stopped

Last Edited
23/01/2019

Condition category
Signs and Symptoms

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0192151055, 12892/001/001/DDX13911

Study information

Scientific Title

A randomised, double-blind, placebo controlled, cross-over trial with low dose amitriptyline in the management of midfacial segment pain

Study objectives
Do patients who have Midfacial Segment Pain (a version of tension type headache that affects the midface) respond to low dose amitriptyline?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee approval 12/07/2004 but trial not started until 26/07/2006 because of delay in provision of a placebo

Primary study design
Interventional

Study design
Randomised double-blind placebo-controlled cross-over trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Signs and Symptoms: Facial pain

Interventions
1. Amitriptyline 20mg
2. Placebo

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Response to pain

Key secondary outcome(s)
1. Analgesic intake
2. Change in headache/facial pain days per week 1 month before trial and on week 8 of study and the same after cross-over
3. Change in mean week severity scores per week 1 week before trial and on week 8 of study and the same after cross-over
4. Change in mean headache/facial pain duration per day

5. Change in number of analgeasic doses or change in number of days analgesic taken
6. Response rate (i.e., proportion of patients with >50% reduction in headache days or headache duration

Completion date
31/12/2015

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Male and females 18-65 at entry into trial
2. Total history of 6 months or more for bilateral symmetrical facial pain (pressure, tight, ache in quality) affecting any of the following in isolation or combination: bridge of nose, periorbital, retro-orbital, either side of the nose, maxilla and forehead
3. Episodes last more than 4 hours, occurring with a frequency of >15 days/month or more 4. No association with changes in ambient pressure
5. Absence of migraninous aura, absence of rhinological symptoms, absence of facial flushing or lacrimation, absence of nasal endoscopic evidence of middle meatal disease, absence of computed topographic evidence of sinonasal inflammatory changes, absence of temporomandibular joint dysfucntion or dental disease
6. Absence of a history of other headache syndromes unless attacks distinguished by patient and frequency less than or equal to 1 month, absences of a history of a history of facial trauma
7. No evidence of an affective disorder on the Hamilton rating scale, not taking an antidepressant or psychotropic drug, no substance abuse
8. No contraindication to taking amitriptyline, no comcomitant drug use of drugs for the prophylactic treatment of headache, alcohol abuse, analgesic abuse

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria

Added June 2008:
1. No association with changes in ambient pressure (diving, flying)
2. Absence of migrainous aura
3. Absence of rhinological symptoms (nasal obstruction, rhinorrhoea, hyposmia/anosmia, discoloured mucus)
4. Absence of facial flushing or lacrimation
5. Absence of nasal endoscopic evidence of middle meatal disease (mucopus, mucosal swelling or oedema)
6. Absence of computed topographic evidence of sinonasal inflammatory changes (mucosal thickening of >3mm)
7. Absence of temporomandibular joint dysfunction or dental disease
9. Absence of a history of other headache syndromes (eg migraine) unless attacks distinguished by patient and frequency less than or equal to 1/month
9. Absence of a history of facial trauma
10. No evidence of an affective disorder on the Hamilton rating scale
11. Not taking an antidepressant or psychotropic drug
12. No substance abuse
13. No contraindication to taking amitriptyline
14. No concomitant drug use of : drugs for the prophylactic treatment of headache, alcohol abuse, analgesic abuse

Date of first enrolment
26/07/2004

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Nottingham University Hospitals NHS Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration