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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	Recruitment status	[ ] Prospectively registered
30/09/2005	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/01/2019	Signs and Symptoms	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
Response to pain

Secondary outcome measures
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

Overall study start date
26/07/2004

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

Age group

Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Added June 2008: 50 patients

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health

Sponsor details
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Sponsor type
Government

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

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

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