

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 23/01/2019	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof A Sama

Contact details

Department of Otorhinolaryngology
Queens Medical Centre
University Hospital NHS Trust
Nottingham
United Kingdom
NG7 2UH

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Anshul.Sama@nottingham.ac.uk

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

Study design

Randomised double-blind placebo-controlled cross-over trial

Primary study design

Interventional

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 analgesic 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 migrainous 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 dysfunction 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, absence 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 concomitant 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