ISRCTN74414962 https://doi.org/10.1186/ISRCTN74414962

Does acupuncture enhance the pain relief of chronic temporomandibular pain dysfunction syndrome (TMPDS) when combined with a the usual standard regime of resting splints and physiotherapy

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 26/04/2011	**Condition category** Digestive System	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0226132754

Study information

Scientific Title

Study objectives
If the addition of acupuncture to established treatment regimes for TMPDS:
1. Enhances pain relief over the short and long term (1 year)
2. Improves patient satisfaction with treatment
3. Is a cost effective addition to treatment in the long term

It also aims to quantify the reduction in medication use: a potential cost saving to the NHS

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Temporomandibular disorder (TMD)

Interventions
1. Acupuncture combined with the usual standard regime of resting splints and physiotherapy
2. Usual standard regime of resting splints and physiotherapy alone

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Pain relief

Secondary outcome measures
No secondary outcome measures

Overall study start date
23/01/2003

Completion date
06/06/2004

Eligibility

Key inclusion criteria
30 patients with facial pain of temporomandibular or myofacial origin from the referrals to the consultants at the Maxillofacial Clinic (Mr JR Tuffin, Mr M Patel and Mr K Sanders) and 30 controls (recruited using randomly generated numbers).

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
1. Patients who have had surgery to the TMJ/head/neck or radiotherapy
2. Contradiction to the techniques: acupuncture/severe needle phobia, uncontrolled anti-coagulation/stainless steel allergy
3. Non-consenting patients
4. Unclear diagnosis
5. Dystonic facial muscles

Date of first enrolment
23/01/2003

Date of final enrolment
06/06/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South Manchester University Hospitals NHS Trust
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Department of Health

Sponsor details
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
South Manchester University Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding (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