Acupuncture Randomised Trial in patients with Tension-Type Headache

Submission date Recruitment status [] Prospectively registered 11/10/2004 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 11/01/2005 Completed [X] Results [] Individual participant data **Last Edited** Condition category 19/08/2009 Nervous System Diseases

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

ART-TTH

Study objectives

Added 19/08/09:

The aim of this study is to investigate the effectiveness of acupuncture compared with minimal acupuncture and with no acupuncture in patients with tension-type headache.

As of 19/08/09 this record has been updated. To investigate the effectiveness of acupuncture compared with minimal acupuncture and with no acupuncture in patients with tension-type headache. All updates can be found under the relevant field with the above update date.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 19/08/09: Received from local medical ethics committies

Study design

Multicentre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Tension-type headache

Interventions

Acupuncture versus minimal acupuncture versus waiting list

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Added 19/08/09:

Difference in numbers of days with headache between the four weeks before randomisation and weeks 9-12 after randomisation, as recorded by participants in headache diaries.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2002

Completion date

31/08/2004

Eligibility

Key inclusion criteria

296 patients with epidosic or chronic tension-type-headache (according to the criteria of the International Headache Society)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

296

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/03/2002

Date of final enrolment

31/08/2004

Locations

Countries of recruitment

Germany

Study participating centre Centre for Complementary Medicine Research Munich Germany 80801

Sponsor information

Organisation

Munich Technical University, Centre for Complementary Medicine Research (Germany)

Sponsor details

Technische Universitaet Munich Kaiserstr. 9 Munich Germany 80801 +49 (0)89 726697 11 ZnF@lrz.tu-muenchen.de

Sponsor type

University/education

ROR

https://ror.org/02kkvpp62

Funder(s)

Funder type

Government

Funder Name

German statutory sickness funds (Ersatzkassen) (Germany)

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 summaryNot provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------|--------------------|--------------|------------|----------------|-----------------|
| Results article | results | 13/08/2005 | | Yes | No |
| <u>Protocol article</u> | treatment protocol | 01/12/2005 | | Yes | No |