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Efficacy and safety of acupuncture for chronic pain caused by tension-type headache: a multi-centre randomised controlled clinical trial

Submission date	Recruitment status	[ ] Prospectively registered
08/06/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/06/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/09/2009	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.gerac.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1748

Study information

Scientific Title

Acronym
Gerac-sks

Study objectives
The aim of the study is to evaluate the efficacy of Chinese acupuncture = TCM acupuncture (verum) in comparison to sham-acupuncture and standard therapy (drug therapy with amitriptyline) in tension-type headache.

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
Multi-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Tension-type headache

Interventions
Chronic pain sufferers (tension-type headache) are randomly allocated to one of the three treatment groups (verum acupuncture, sham acupuncture, or established standard therapy = amitriptyline).

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
The binary endpoint is success, yes or no, 6 months after randomization. Success is defined as a reduction of the number of headache days per month of more than 50% in comparison with the number per month at baseline.

Secondary outcome measures
Pain intensity, von Korff Score, health-related quality of life (12-Item Short-Form Health Survey SF-12), Global Patient Assessment, number of adverse and severe adverse events, quality parameters e.g. the assessment of patients blindness to the mode of acupuncture (by asking the patient to guess their group assignment after the last follow up)

Overall study start date
29/04/2002

Completion date
15/06/2005

Eligibility

Key inclusion criteria
Signed informed consent, aged 18-65, diagnosis of tension-type headache according to the criteria of the International Headache Society, tension-type headaches for >6 months, at least 10 headache days per month during the last 4 weeks before randomization (completed baseline headache diary), each day is rated as a headache day if headaches persisted for at least 4 hours or if the administration of analgesics is necessary to attenuate the pain, von Korff Chronic Pain Score at least Grade I, ability to speak and read German (to understand the questionnaires and telephone interviews).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants

945

Key exclusion criteria
Additional migraines for more than 1 day per month, secondary headaches, additional chronic pain as a result of other additional diseases, prophylaxis of headaches with drugs during the last 12 months, modification of a permanent analgesic therapy, or a new cortison-therapy within the last 8 weeks before randomization, abuse of drugs or pain medication, any acupuncture treatment against tension-type headaches at any time, or previous treatment with needle-acupuncture in any other indication in the last year.

Date of first enrolment
29/04/2002

Date of final enrolment
15/06/2005

Locations

Countries of recruitment
Germany

Study participating centre
Bürkle de la Camp Platz 1
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Sponsor information

Organisation
Ruhr-University Bochum (Germany)

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Sponsor type
University/education

Website

http://www.amib.ruhr-uni-bochum.de/

ROR
https://ror.org/04tsk2644

Funder(s)

Funder type
Industry

Funder Name
German public health insurance providers: AOK, BKK, IKK, Bundesknappschaft, Bundesverband der Landwirtschaftlichen Krankenkassen, and Seekasse (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 summary
Not provided at time of registration