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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
08/06/2005

Recruitment status
No longer recruiting

Registration date
29/06/2005

Overall study status
Completed

Last Edited
11/09/2009

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

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
Bochum
Germany
44789

Sponsor information

Organisation
Ruhr-University Bochum (Germany)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes