

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

<b>Submission date</b> 08/06/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/06/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/09/2009	<b>Condition category</b> 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

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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

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes