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Efficacy and safety of acupuncture in Chronic MIGraine

Submission date	Recruitment status	[_] Prospectively registered
28/06/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/08/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/10/2017	Nervous System Diseases	

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
2001-006

Study information

Scientific Title
Efficacy and safety of acupuncture in Chronic MIGraine - a multicentre, randomised, controlled clinical trial

Acronym
gerac-MIG

Study objectives
The goal of the trial is to assess the efficacy of standardised acupuncture (verum-acupuncture) in the treatment of chronic migraine in comparison to standardised sham-acupuncture and to standard therapy regarding the reduction of migraine days 26 weeks after start of treatment. Secondary endpoints are the subjective estimation of the therapies through the patient and safety of the therapies.

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Migraine

Interventions
Chronic pain sufferers (migraine) are randomly allocated to one of the three treatment groups:
1. Verum-acupuncture
2. Sham-acupuncture
3. Established standard therapy

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Primary endpoint is to assess the efficacy of standardised acupuncture (verum-acupuncture) in the treatment of chronic migraine in comparison to standardised sham-acupuncture and to standard therapy regarding the reduction of migraine days 26 weeks after start of treatment.

Secondary outcome measures
Secondary endpoints are:
1. Change in days of migraine 12 weeks after start of treatment
2. Migraine intensity
3. Intake of acute-medication
4. 12-item Short Form health survey (SF-12)
5. Von-Korff-Pain-Scale
6. Global Patient Assessment
7. Economic and quality parameters

Overall study start date
25/04/2002

Completion date
15/06/2005

Eligibility

Key inclusion criteria
1. Member of participating health insurance company
2. Age between 18 and 65
3. Signed informed consent
4. Ability to read and speak sufficient German
5. First migraine attack before the age of 50
6. First migraine diagnosis at least six months before
7. Two to six migraine attacks in four weeks
8. Duration of migraine attacks 4 to 72 hours without acute-medication or at least 2 hours with acute-medication
9. Two migraine characteristics have to be met, at least one accompaniment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
1295

Key exclusion criteria
1. Severe migraine-attacks with inability to go to work on more than four days a month
2. Other neurological disease
3. Seconday headache
4. Neuralgia of the face or head
5. More than six days of non-migrainous headache a month
6. Experience with acupuncture against migraine
7. Any acupuncture in the last 12 months
8. Previous unsuccessful therapy with beta-blocker
9. Drug abuse
10. Pregnancy
11. Nursing mother
12. Insufficient contraception
13. Intake of antipsychotic or antidepressant drugs
14. Participation in another clinical trial
15. Intake of analgesics on more than three days a month because of other chronic pain
16. Use of prophylactic migraine medication in the last six months
17. Ongoing cortisone therapy
18. Epilepsy
19. Manifest psychiatric disease

Date of first enrolment
25/04/2002

Date of final enrolment
15/06/2005

Locations

Countries of recruitment
Germany

Study participating centre
University Essen
Essen
Germany
45122

Sponsor information

Organisation

Ruhr-University Bochum (Germany)

Sponsor details
c/o Prof. Dr. H.J. Trampisch
Universitaetsstr. 150
Bochum
Germany
44780

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/06/2005		Yes	No
Results article	results	01/04/2006		Yes	No