ISRCTN65814467 https://doi.org/10.1186/ISRCTN65814467

Efficacy and safety of acupuncture for the treatment of non-specific acute low back pain: a randomised controlled multicentre trial

Submission date
21/02/2006

Recruitment status
No longer recruiting

Registration date
22/02/2006

Overall study status
Completed

Last Edited
04/06/2019

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
PI051191

Study information

Scientific Title

Efficacy and safety of acupuncture for the treatment of non-specific acute low back pain: a randomised controlled multicentre trial

Acronym
Acute-LBP & Acupuncture

Study objectives
Acupuncture is capable of reducing pain and incapacity among patients suffering non-specific acute low back pain better than sham acupuncture (applied at non-specific points), placebo acupuncture and conventional treatment. Moreover, the application of this technique reduces the duration of absence from work caused by non-specific acute low back pain, while at the same time moderating the consumption of medicines used as conventional therapy and reducing the iatrogeny caused by such medicines without provoking any significant iatrogeny of its own.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethical validity of this study has been analysed by the Andalusian Regional Committee for Clinical Trials, after approval by the Research Committee at each of the healthcare clinics concerned, date 29/06/2005

Study design
Randomised, four-branch, multicentre, prospective study.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-specific acute low back pain

Interventions
1. Semi-standardised real acupuncture (group A)
2. Sham acupuncture (acupuncture at non-specific points) (group B)
3. Placebo acupuncture (group C)
4. Conventional treatment (group D)

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Clinically Relevant Improvement (CRI) of the lumbar complaint at three weeks after randomisation. We define CRI as a reduction of 35% or more in lumbar incapacity as reported on the Roland-Morris questionnaire

Key secondary outcome(s))
CRI at 12 and 48 weeks after randomisation and a series of result measures (pain intensity, improvement perceived by the patient, incapacity to work, quality of life [EuroQol 5D] and consumption of analgesics) used to reflect the multidimensional nature of the impact of low back pain, obtained at 3, 12 and 48 weeks after beginning the treatment.
Other secondary measures to be used are: a control scale of the credibility of the treatment after the first week of treatment, for groups A, B and C, the pain intensity before and immediately after each of the treatment sessions, the record of the collateral effects and adverse reactions that may appear up to week 3 (during the treatment phase), the number of new episodes of low back pain reported at weeks 12 and 48, and the number of days of enforced absence from work because of low back pain from the date of final assessment to weeks 12 and 48.

Completion date
30/01/2008

Eligibility

Key inclusion criteria
1. Signed informed consent form
2. New episode of non-specific acute low back pain of less than two weeks evolution, with or without irradiation (diagnosed by clinical history and physical examination). We define new as the first episode in at least the last six months.
3. Patients of working age (whether in paid employment or not), either occupationally active or absent from work because of back pain
4. No previous treatment with acupuncture (in order to minimise the possibility of patients being able to distinguish the real acupuncture treatment from the various control (placebo) modes

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
275

Key exclusion criteria
1. More than one absence from work because of back pain within a period of six months (in order to eliminate possible mercenary motives)

2. The presence of alarm signs that suggest the protrusion or prolapse of one or more intervertebral disks with concurrent neurological symptoms, infectious spondylopathy, previous surgery affecting the spine, low back pain caused by inflammatory illness, whether malign or

autoimmune, congenital deformities of the spine except for slight scholiosis or lordosis, vertebral fractures, stenosis of the spinal canal, spondylolysis or spondylolisthesis

3. Contraindications for acupuncture such as extensive skin disorders, treatment with anticoagulants, or pregnancy

4. Inability to complete the questionnaires or to answer the questions of the assessor

Date of first enrolment
20/02/2006

Date of final enrolment
30/01/2008

Locations

Countries of recruitment
Spain

Study participating centre
Unidad de Tratamiento del Dolor
Dos Hermanas (Sevilla)
Spain
41700

Sponsor information

Organisation
Department of Health and Consumption - Institute of Health Carlos III (Spain)

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Government

Funder Name
Institute of Heath Carlos III, Ministry of Health and Consumption (Instituto de Salud Carlos III, Instituto de Salud y Consumo) (Spain)

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?
Results article	results	01/09/2012	04/06/2019	Yes	No
Protocol article	Protocol	21/04/2006		Yes	No