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# Randomised controlled study in the primary healthcare sector to investigate the effectiveness and safety of auriculotherapy for the treatment of uncomplicated chronic rachialgia

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| **Submission date**<br>29/05/2008 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>05/06/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>28/02/2014 | **Condition category**<br>Musculoskeletal Diseases | |

**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**
07/90058-0046/2007

# Study information

## Scientific Title

## Study objectives
The auriculotherapy using implants with vaccaria seeds is more effective than placebo, with respect to the pain intensity, experienced by patients with uncomplicated chronic rachialgia.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Andalusian Government Committee for Clinical Trials. Date of approval: 07/12/2007 (ref: acta 10 /07)

## Study design
Randomised controlled multicentre prospective study, with two parallel arms.

## Primary study design
Interventional

## Study type(s)
Screening

## Health condition(s) or problem(s) studied
Uncomplicated chronic musculoskeletal rachialgia (neck, mid-back or lower back)

## Interventions
True auriculotherapy using pressure with vaccaria seeds (TAP):
Application of auricular implants with vaccaria seeds (vaccaria segetalis Garcke, known in China as Wang bu liu xing) as an individualised form of sensory stimulation, affixed to the auricular pavilion by means of flesh-coloured sticking plaster. Selection of the auricular points will be made in accordance with the pain characteristics and the sensitivity of the auricular zones, examined using a 250 gr pressure detector. The patients will be requested to squeeze the implant with their finger 10 times, 3 times a day. A new implant will be inserted every week for 8 weeks.

Placebo auriculotherapy (PAP):
The same protocol will be followed, under the same conditions as for TAP, but with the application of sticking plaster over inactive black plastic discs, with a diameter of 1.5 mm, simulating the appearance of the auricular implants used in the TAP.

Any adverse reactions or side effects that may occur will be recorded in the corresponding data logbook, stating details of the reaction, and date of occurrence. The same amount of time should be dedicated to the patients in each of the two groups, as well as for the pre and post-session evaluations. The patients in both groups will be called 8 times for treatment (once a week) for the auricular implants to be inserted (Total duration of interventions: 8 weeks).

## Intervention Type

Other

### Phase
Not Specified

### Primary outcome(s)
Changes in pain intensity, measured on the 100 mm visual analogue scale (VAS), at 9 weeks after beginning treatment

### Key secondary outcome(s))
1. Changes in pain intensity, measured on the 100 mm VAS, at 6 months after beginning treatment
2. Changes in the McGill Pain Questionnaire (MPQ), at the end of treatment and after 6 months
3. Satisfaction on the improvement perceived by the patient, measured at 9 weeks
4. Changes in health-related quality of life, according to the Spanish version of the 12-item Short Form health survey, version 2, at the end of treatment and after 6 months
5. Changes in the results of the Lattinen test and in the consumption of analgesics and NSAIDs (whether or not prescribed by the GP), at the time of randomisation, after each treatment session, at the end of treatment and after 6 months

### Completion date
20/12/2009

## Eligibility

### Key inclusion criteria
1. Both males and females, aged at least 18 years
2. Uncomplicated chronic muscular-skeletal rachialgia (neck, mid-back or lower back), diagnosed by clinical background and physical examination
3. Have not previously received treatment with auricular implants

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Protrusion or prolapse of one or more intervertebral discs with concurrent neurological symptoms
2. Infectious spondylopathy

3. Previous surgery of the spinal column
4. Rachialgia caused by inflammatory disease, malign or autoimmmune
5. Congenital deformities of the spinal column, except mild degrees of scoliosis or lordosis
6. Vertebral fractures
7. Spinal stenosis
8. Spondylolysis or spondylolystesis
9. Skin complaints in the auricular pavilion or allergy to sticking plaster
10. Pregnancy
11. Lawsuits brought by reason of rachialgia
12. Incapacity to fill in the questionnaires or respond to the evaluator's questions

**Date of first enrolment**
01/05/2008

**Date of final enrolment**
20/12/2009

# Locations

**Countries of recruitment**
Spain

**Study participating centre**
**Pain Treatment Unit**
Dos Hermanas
Spain
41700

# Sponsor information

**Organisation**
Carlos III Health Institute (Spain)

**ROR**
https://ror.org/00ca2c886

# Funder(s)

**Funder type**
Research organisation

**Funder Name**

Healthcare Research Fund of the Carlos III Health Institute (Project no. PI0790058) (Spain)

**Funder Name**
Andalusian Regional Ministry of Health (Project no. 0046/2007)

# 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 | 01/06/2014 | | Yes | No |
| Protocol article | protocol | 06/07/2008 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |