

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

Submission date

29/05/2008

Recruitment status

No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date

05/06/2008

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

28/02/2014

Condition category

Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet.

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 measure

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

Secondary outcome measures

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

Overall study start date

01/05/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400

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 autoimmune
5. Congenital deformities of the spinal column, except mild degrees of scoliosis or lordosis
6. Vertebral fractures
7. Spinal stenosis
8. Spondylolysis or spondylolysis
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)

Sponsor details

C/ Sinesio Delgado, 6
Madrid
Spain
28029

Sponsor type

Research organisation

Website

<http://www.isciii.es/htdocs/en/index.jsp>

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**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	06/07/2008		Yes	No
Results article	results	01/06/2014		Yes	No