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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

Submission date
29/05/2008

Recruitment status
No longer recruiting

Registration date
05/06/2008

Overall study status
Completed

Last Edited
28/02/2014

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

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 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)

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