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Effect of acupuncture in pain relief and functional improvement in ankylosing spondylitis: a randomized controlled trial

Submission date
31/01/2008

Registration date
13/02/2008

Last Edited
28/03/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
Project number at Institute of Orthopaedics and Traumatology: 371

Study information

Scientific Title

Study objectives

To evaluate the efficacy of acupuncture for spinal pain relief in patients diagnosed with Ankylosing Spondylitis (AS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University Hospital, University of Sao Paulo, School of Medicine, approved on 8 October 2003 (CAPPESQ number: 769-03)

Study design
Prospective, double-blind, randomised placebo-controlled trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pain relief in patients diagnosed with ankylosing spondylitis

Interventions
Randomization was performed using colored balls. Patients rated their pain intensity using VAS, disease activity, and function level at baseline.

Patients were randomly allocated to one of two treatment groups:

Group A: Classical acupuncture. Participants received classical acupuncture treatment associated with the use of NSAIDs and analgesics. Disposable, sterilized, stainless steel 0.25 mm x 40 mm length needles were employed. 10 acupuncture sessions, twice weekly, 20 minutes per session. Each patient was treated in a separate room.

Group B: Sham acupuncture. Participants received NSAIDs and analgesics together with non-invasive sham electro acupuncture, which was performed using inactive surface electrodes with audiovisual biofeedback reinforcement, touching patient's skin for seven seconds. 10 acupuncture sessions, twice weekly, 20 minutes per session. Each patient was treated in a separate room.

Acupuncture points employed in both groups: GV20b, SI3b, BL62b, GB34b and Ex-B2b

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The following were assessed before and immediately after the interventions:
1. Patient's assessment of spinal pain (0-10 cm VAS).

2. Patient's global assessment of disease-activity and function (Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] and Bath Ankylosing Spondylitis Functional Index [BASFI]). The BASDAI measures the severity of fatigue, spinal and peripheral joint pain, localized tenderness, and morning stiffness, assessed on a 10 cm VAS. The BASFI measures the functional status of AS patients, and is also assessed on a 10 cm VAS.
3. Acute-phase reactants (C-Reactive Protein, Erythrocyte Sedimentation Rate [ESR], Immunoglobulin A [IgA])
4. Number of analgesic pills per week

Key secondary outcome(s))
Subjective assessment of pain, performed before and immediately after the interventions, using a 7-point Likert scale, where 1 = much worse, 2 = moderately worse, 3 = slightly worse, 4 = no effect, 5 = small improvement, 6 = moderate improvement, 7 = great improvement.

Completion date
15/01/2004

Eligibility

Key inclusion criteria
1. Age range between 20 and 60 years
2. Painful complaints in the axial line
3. Patients who have not received any Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or analgesics for three months prior to the inclusion into this trial
4. Those who are referred to the Rheumatology Service, University of São Paulo, University Hospital, School of Medicine with diagnosis of ankylosing spondylitis according to the New York 15 and European 16 criteria for spondyloarthropathies
5. A mean baseline Visual Analogue Scale (VAS) score >= 4 for pain

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Severe psychiatric disease
2. Sensory or motor neurological deficits
3. Fibromyalgia
4. Previous treatment with acupuncture
5. Unable to visit the hospital for treatment

Date of first enrolment
01/05/2003

Date of final enrolment
15/01/2004

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Guaramembé, 589
Sao Paulo
Brazil
01308-050

Sponsor information

Organisation
University of São Paulo (Brazil)

ROR
https://ror.org/036rp1748

Funder(s)

Funder type
University/education

Funder Name
University of São Paulo, University Hospital (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration