

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

Submission date 31/01/2008	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 13/02/2008	Overall study status Completed	☐ Protocol
Last Edited 28/03/2008	Condition category Musculoskeletal Diseases	☐ 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

Contact name

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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)

Primary study design

Interventional

Study design

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

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