ISRCTN34405634 https://doi.org/10.1186/ISRCTN34405634

An inert and active control acupuncture needle with potential for randomised, double-blind (practitioner-patient blinding), placebo controlled trial - a validation study

Submission date
28/08/2009

Recruitment status
No longer recruiting

Registration date
11/09/2009

Overall study status
Completed

Last Edited
11/09/2009

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

Study information

Scientific Title

Study objectives

The double-blind placebo needle could be effective in a randomised clinical acupuncture trial in which multiple placebo needles are administered as treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of Showa University, School of Medicine on the 24th December 1999 (ref: 65).

Primary study design
Interventional

Study design
Randomised double-blind placebo-controlled single-centre study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healthy subjects with stiff neck

Interventions
Mean age: 32.1 ± 9.9 years, 31 males, 25 females
Aim: To assess whether the double-blind placebo needle is effective in a randomised clinical acupuncture trial in which multiple placebo needles are administered as treatment.
Interventions: Non-penetrating control needles which the needle tip did not reach the skin (control), non-penetrating placebo needles which the needle tip pressed against the skin (placebo) and the penetrating (verum) needles.

In this trial, each of 6 acupuncturists (mean +/- SD year: 12.5 ± 11.8 years) applied acupuncture treatment to 20 patients. For each treatment, the acupuncturist applied 4 needles to the subject's shoulder. After completion of treatment with 4 needles, the practitioner and subject were asked to record whether the treatment was "non-penetrating control," "non-penetrating placebo", "penetrating", or "unidentifiable." After the treatment, the subjects were asked on their improvement in intensity of stiff neck on a Visual Analogue Scale (VAS) ranging from -100 (the most intense stiff neck in the past) to 0 (no improvement) to 100 (no stiff neck). One treatment and no follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Numbers of correctly, incorrectly and unidentified treatments by practitioners and subjects.

Key secondary outcome(s)
Improvement of stiff neck on a VAS (0-100) immediately after treatment.

Completion date
24/02/2009

Eligibility

Key inclusion criteria
1. Both males and females
2. Healthy volunteers
3. Age range: 18-70 years

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Key exclusion criteria
Unhealthy volunteers

Date of first enrolment
26/01/2009

Date of final enrolment
24/02/2009

Locations

Countries of recruitment
Japan

Study participating centre
2-9-1 Ariake Koto-ku
Tokyo
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135-0063

Sponsor information

Organisation
Hanada College (Japan)

ROR
https://ror.org/0373a6k33

Funder(s)

Funder type
University/education

Funder Name
Hanada College (Japan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration