

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	<input type="checkbox"/> Prospectively registered
Registration date 11/09/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/09/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Nobuari Takakura

Contact details

2-9-1 Ariake Koto-ku

Tokyo

Japan

135-0063

+81 3 6703 7016

takakura@t-ariake.ac.jp

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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).

Study design

Randomised double-blind placebo-controlled single-centre study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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 \pm 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 measure

Numbers of correctly, incorrectly and unidentified treatments by practitioners and subjects.

Secondary outcome measures

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

Overall study start date

26/01/2009

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

120

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

Japan

135-0063

Sponsor information

Organisation

Hanada College (Japan)

Sponsor details

20-1 Sakuragaoka-machi Shibuya-ku

Tokyo

Japan

150-0031

+81 3 3461 4787

m-hanada@hanada.ac.jp

Sponsor type

University/education

Website

<http://www.hanada.ac.jp/>

ROR

<https://ror.org/0373a6k33>

Funder(s)

Funder type

University/education

Funder Name

Hanada College (Japan)

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