

Double-blind (practitioner-patient masking) trial of acupuncture needles: does patient reaction reveal needle authenticity?

Submission date 15/05/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/07/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 03/07/2008	Condition category Other	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Research for effects of acupuncture stimulation on somatosensory function and somatic nerve reflex

Study objectives

In our previous study (<http://www.ncbi.nlm.nih.gov/pubmed/17925042>) we demonstrated that the penetrating and non-penetrating needles that we have developed can successfully be used to conduct a practitioner-blinded acupuncture trial. However, it is possible that the penetrating needle occasionally elicits pain in the patient, and the reaction of the patient can reveal the authenticity of the needle to the practitioner. In the current study, we aimed to determine the frequency in which the pain elicited by the penetrating needle and the reaction of the patient reveal authenticity of the needle to the practitioner.

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

Double-blind, placebo-controlled, single-centre study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Healthy subjects

Interventions

24 men and 6 women were recruited, mean (SD) age = 31.0 (9.8) years.

This study was conducted to determine the frequency in which the penetrating needle elicits pain in the participant, and whether the participant reaction to the pain serves as a significant clue in revealing the authenticity of the needle in a practitioner-blinded acupuncture trial.

In this trial, although only penetrating needles were actually provided, the acupuncturist was told that he was provided with a mixture of penetrating and non-penetrating needles. The acupuncturist then applied a pair of needles at the bilateral TE-5 points, one needle on each side, in the 30 subjects using the alternating twirling technique. Following each needle application, the acupuncturist recorded whether he thought the needle was a penetrating or non-penetrating needle, and the clues that led him to his decision (e.g., the participant's facial expression, body movement, verbal expression) and the level of confidence in his decision.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The practitioner recorded the following after each needle application:

1. Clues that led to acupuncturist's identification of authenticity of the needle, these included facial expression, body movement, verbal expression, bleeding, and no bleeding, in addition to the feeling of needle insertion and feeling of needle removal.
2. Acupuncturist's confidence in identification of needle authenticity (i.e., the degree of certainty about his judgment) on a numerical rating scale (0 for no confidence and 100 for complete confidence)

Secondary outcome measures

Subjects' identification of the authenticity of the needles.

Overall study start date

01/09/2002

Completion date

25/12/2002

Eligibility**Key inclusion criteria**

1. Both males and females
2. Healthy volunteers
3. Age range: 18 - 55 years

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

Key exclusion criteria

Unhealthy volunteers

Date of first enrolment

01/09/2002

Date of final enrolment

25/12/2002

Locations

Countries of recruitment

Japan

Study participating centre

20-1 Sakuragaoka-Machi

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Japan

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Sponsor information

Organisation

Hanada College (Japan)

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Sponsor type

University/education

Website

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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