

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 03/07/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 03/07/2008	<b>Condition category</b> 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

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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)

**Key secondary outcome(s)**

Subjects' identification of the authenticity of the needles.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**  
Tokyo  
Japan  
150-0031

## **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