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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 03/07/2008	**Overall study status** Completed	
Last Edited 03/07/2008	**Condition category** Other	

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 practitoner 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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Sponsor information

Organisation
Hanada College (Japan)

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Sponsor type
University/education

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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