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Needle penetration versus placebo device: Double-Blind Acupuncture trial

Submission date 08/12/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 26/01/2007	**Overall study status** Completed	
Last Edited 12/09/2011	**Condition category** Signs and Symptoms	

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

Acronym
DBAS

Study objectives
Needle penetration of acupuncture has specific analgesic effect over placebo acupuncture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from The Showa University Ethics Committee on the 24 December 1999 (ref: 65).

Study design
A crossover design with real-acupuncture and placebo-acupuncture.

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 volunteers, no disease

Interventions
A placebo needle, which cannot penetrate the skin, and a real needle, which can penetrate the skin.

Intervention Type
Device

Phase
Not Specified

Primary outcome measure
Amount of pain eliciting painful electrical stimulation on a Visual Analogue Scale (VAS).

Secondary outcome measures
Intensity of needle sensations on a VAS.

Overall study start date
01/07/2000

Completion date
01/07/2005

Eligibility

Key inclusion criteria
Healthy volunteers familiar with acupuncture treatment.

Participant type(s)
Healthy volunteer

Age group
Not Specified

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Unhealty volunteers
2. Healthy volunteers unfamiliar with acupuncture treatment

Date of first enrolment
01/07/2000

Date of final enrolment
01/07/2005

Locations

Countries of recruitment
Japan

Study participating centre
20-1 Sakuragaoka-Machi
Tokyo
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Sponsor information

Organisation
Hanada College (Japan)

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Sponsor type
University/education

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