Needle penetration versus placebo device: Double-Blind Acupuncture trial

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 Japan 150-0031

Sponsor information

Organisation

Hanada College (Japan)

Sponsor details

20-1 Sakuragaoka-Machi Shibuya-ku Tokyo Japan 150-0031 +81 (0)3 3461 4787 takakura@hanada.ac.jp

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