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Effect of acupuncture treatment on stiff neck

Submission date
22/02/2011

Registration date
10/03/2011

Last Edited
27/12/2023

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There have been no reported randomized placebo-controlled trials investigating the effectiveness of acupuncture under double-blind conditions using practitioner-patient blinded needles. The aim of this study is to verify the effectiveness of acupuncture for functional neck /shoulder stiffness.

Who can participate?
Patients aged over 18 with stiff neck not from organic disease.

What does the study involve?
Before treatment, patients will be asked about the intensity of their stiff neck. Patients will be randomly allocated to receive one of the following four acupuncture treatments:
1. Treatment with penetrating needles
2. Treatment with skin-touch placebo needles (the needle tip presses against the skin)
3. Treatment with no-touch placebo needles (the needle tip does not reach the skin)
4. Treatment without any needle applications (control group)
Immediately after and 24 hours after treatment, the patients are asked about the intensity of their stiff neck. Also, the acupuncturists and patients are asked to record whether the treatment is 'no-touch control', 'skin-touch placebo', 'penetrating', or 'unidentifiable'.

What are the possible benefits and risks of participating?
Participants will contribute to developing acupuncture and moxibustion studies. Although rare, there is the possibility of needle pain, unpleasantness, bleeding and hematoma with acupuncture.

Where is the study run from?
Tokyo Ariake University of Medical and Health Sciences (Japan).

When is the study starting and how long is it expected to run for?
The study started in June 2010 and will run until March 2015.

Who is funding the study?
Grants-in-Aid for Scientific Research (B) (Japan).

Who is the main contact?
Prof Nobuari Takakura

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RCT

Study information

Scientific Title
Effect of acupuncture treatment on stiff neck: a randomised, double-blind, placebo-controlled trial

Study objectives
Differences exist in therapeutic effect on stiff neck between treatments with the penetrating, skin-touch placebo, no-touch control needle and a control group without any needles. The aim of the study is to assess whether verum penetrating needle treatment has specific effect over placebo needle treatment on stiff neck.

On 23/07/2014 the following changes were made to the trial record:
1. The overall trial start date was changed from 24/01/2011 to 09/06/2010.
2. The overall trial end date was changed from 31/03/2013 to 31/03/2015.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Tokyo Ariake University of Medical and Health Sciences, 08/07/2010

Study design
Randomised double-blind placebo-controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Musculoskeletal discomfort

Interventions
Treatments using the double-blind needle:
1. The no-touch needle which the needle tip does not reach the skin
2. Skin-touch placebo needle which the needle tip presses against the skin
3. Verum penetrating needle
4. Treatment without any needle applications (control group)

Before treatment, patients are asked about the intensity of their stiff neck on a visual analogue scale. In this trial, each of five acupuncturists applies acupuncture treatment to 60 patients. For each treatment, the acupuncturist applies four needles to four acupoints on the neck and shoulder in the patients. Immediately after and 24 hours after treatment, the patients are asked about the intensity of their stiff neck on a visual analogue scale. Also, acupuncturists (practitioners) and patients are asked to record whether the treatment is 'no-touch control', 'skin-touch placebo', 'penetrating', or 'unidentifiable'. The same methods are applied to the control group without any needles and relating questions are asked.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Improvement in stiff neck: before, immediately and 24 hours after needle application, the patients are asked about the intensity of their stiff neck on a Visual Analogue Scale (VAS) ranging from 0 (no stiff neck) to 100 (the most intense stiff neck imaginable)

Secondary outcome measures

Effect of patient and practitioner blinding using the double-blind needle: after completion of treatment, the practitioners and patients are asked to record whether they think the treatment is 'penetrating', 'skin-touch', 'no-touch' or 'utterly unidentifiable'

Overall study start date
09/06/2010

Completion date
31/03/2015

Eligibility

Key inclusion criteria
1. Patients with stiff neck not from organic disease
2. Age range: over 18 years, both male and female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Total final enrolment
400

Key exclusion criteria
Patients who have:
1. Cervical spondylosis
2. Cervical disc herniation
3. Cervico-omo-brachial syndrome
4. Thoracic outlet syndrome
5. Liver, gallbladder or heart disease
6. High blood pressure
7. Cerebral vascular disease
8. Neurological disease
9. Under any pharmacological treatment
10. Patients who will receive any cure for stiff neck or acupuncture treatment within 24 hours after treatment in this study

Date of first enrolment

24/01/2011

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
Japan

Study participating centre
2-9-1 Ariake, Koto-ku
Tokyo
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135-0063

Sponsor information

Organisation
Japan Society for the Promotion of Science (Japan)

Sponsor details
8 Ichiban-cho, Chiyoda-ku
Tokyo
Japan
102-8472

Sponsor type
Government

Website
http://www.jsps.go.jp/

ROR
https://ror.org/00hhkn466

Funder(s)

Funder type
Government

Funder Name

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/07/2014		Yes	No
Results article		09/12/2023	27/12/2023	Yes	No