

Acupuncture for Sequelae of Bell's Palsy

Submission date 25/06/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 06/07/2010	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 04/06/2015	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

komc mirb 2010 - 01

Study information

Scientific Title

Acupuncture for Sequelae of Bell's Palsy: a randomised wait-list controlled pilot trial

Study objectives

The primary objective of the present protocol is to investigate the effectiveness of acupuncture in patients with sequelae of Bell's palsy, compared to a no-acupuncture waitlist status.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Kyung-Hee University Medical Center Ethics Committee, 11/06/2010

Study design

Randomised assessor blind wait list controlled pilot trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Sequelae of Bell's palsy

Interventions

The study includes the following periods in all groups: a treatment period of 8 weeks (3 sessions /week), and a follow-up period of 4 weeks.

Acupuncture group:

In the acupuncture treatment group, 18 acupuncture points (ipsilateral ST4, ST6 on the unaffected side, ipsilateral ST1, EX-HN4, TE23, LI20 on the affected side, and bilateral TE17, ST9, LI10, LI4, ST36, GB34) will be inserted with 0.20 mm in diameter x 30 mm in length disposal needles. The needle will be inserted to a depth of 5 - 10 mm, according to the points selected. The participating acupuncture doctors will manually manipulate the acupuncture needles with de-qi sensation and maintain the needles for 10 minutes.

Waitlist:

Participants who will be allocated to waitlist will receive no acupuncture treatment throughout the 8 weeks. After 8 weeks, if participants elect to try the acupuncture treatment it will be provided, acupuncture treatment period of 8 weeks (3 sessions/week).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Changes in FDI (Facial Disability Index) after 24 sessions/8 weeks of acupuncture treatment.

Secondary outcome measures

Changes in the following, after 24 sessions/8 weeks of acupuncture treatment and one-month follow-up:

1. Sunnybrook Facial Grading System
2. H-B Scale
3. Lip-length and snout indices
4. Facial stiffness

Overall study start date

01/08/2010

Completion date

30/04/2011

Eligibility**Key inclusion criteria**

1. Aged between 18-65
2. Diagnosis of Bell's palsy (ICD-10 G51.0), at least 6 months prior to recruitment
3. FDI (Facial Disability Index) score of below 70 in Physical Function, and below 80 in Social/Well-being Function
4. Provided written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

20 participants in experiment group (acupuncture treatment), 10 participants in control group (wait list)

Key exclusion criteria

1. Secondary facial palsy resulting from specific disease such as infection, multiple neuritis, tumour invading the temporal region, cerebral contusion or stroke
2. Patient manifesting Ramsay-Hunt syndrome
3. Bilateral facial palsy
4. Recurred facial palsy
5. Received orally administered corticosteroids or anti-viral agent (aciclovir, valaciclovir, famciclovir, ganciclovir) within 1 month before enrolment
6. Received alternative and complementary modality, i.e. acupuncture, moxibustion, vesicant therapy or massage for treating Bell's palsy within 3 months
7. Received operation, i.e. facial nerve decompression, facial nerve and muscle reconstruction for treating Bell's palsy
8. Suffering serious medical condition such as uncontrolled hypertension, diabetes mellitus requiring insulin injection, past or current malignant tumour, severe dyslipidemia or liver and kidney dysfunction, anaemia, active pulmonary tuberculosis, other infectious disease or systemic diseases insufficient for acupuncture treatment
9. Other neurologic illness
10. Participating in another clinical trial
11. Suffering psychiatric illness insufficient for participation in clinical trial
12. Unable to obtain written consent
13. Pregnant or nursing status, or planning conception during treatment
14. Scar in administration area or systemic illness unsuitable for acupuncture treatment in the judgement of the investigator

Date of first enrolment

01/08/2010

Date of final enrolment

30/04/2011

Locations

Countries of recruitment

Korea, South

Study participating centre

Dongdaemun-gu

Seoul

Korea, South

130-702

Sponsor information

Organisation

Kyung Hee University (South Korea)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/01zqcg218>

Funder(s)

Funder type

University/education

Funder Name

Kyung Hee University (South Korea) - Research Fund in 2010 (KHU-20100699)

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	09/03/2011		Yes	No
Results article	results	03/06/2015		Yes	No