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Acupuncture for Sequelae of Bell's Palsy

Submission date	Recruitment status	[X] Prospectively registered
25/06/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/06/2015	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

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)

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

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?
Results article	results	03/06/2015		Yes	No
Protocol article	protocol	09/03/2011		Yes	No