Electrical muscle stimulation for Bell's palsy (sudden weakness in the muscles on one side of the face)

21/02/2023 No longer recruiting [X] Protocol

Registration date Overall study status [X] Statistical analysis plan

27/02/2023 Completed [X] Results

Last Edited Condition category [X] Individual participant data

08/07/2024 Nervous System Diseases

Plain English Summary

Background and study aims

Bell's palsy is sudden weakness in the muscles on one side of the face. The aim of this study is to explore whether selective electrical muscle stimulation could shorten the time to recovery of facial paralysis.

Who can participate?

Adults (aged 18 years or above) with a diagnosis of acute, incomplete Bell's palsy, up to one month from onset of paralysis.

What does the study involve?

The control condition will receive usual physical therapy, consisting of neuromuscular reeducation and massage therapy. The experimental group will receive selective electrical muscle stimulation, in addition to usual physical therapy. For both groups, treatments are received once daily, Monday through Friday, until they are judged by their treating therapist to be fully recovered. At enrollment, discharge, and a follow-up visit 6 months after discharge, all participants will be video recorded performing 11 facial expressions. The video-recorded facial movements will be rated by two independent blinded reviewers using the House Brackmann scale and the eFACE scale.

What are the possible benefits and risks of participating?

All participants receive usual physical therapy, which is the standard of care for Bell's palsy. Half of the participants will receive electrical stimulation, which may decrease time to recovery from paralysis. Electrical stimulation may be associated with increased risk or severity of synkinesis.

Where is the study run from?

Universidad Nacionale del Nordeste, Corrientes, Argentina.

When is the study starting and how long is it expected to run for? February 2017 to December 2018

Who is funding the study? Investigator initiated and funded

Who is the main contact? Myriam Loyo, loyo@ohsu.edu

Contact information

Type(s)

Principal Investigator

Contact name

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Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

${\bf Clinical Trials. gov\ number}$

Nil known

Secondary identifying numbers

30/17

Study information

Scientific Title

Efficacy of adding selective electrical muscle stimulation to usual physical therapy for Bell's palsy

Study hypothesis

Transcutaneously applied selective electrical muscle stimulation, delivered with physical therapy, will accelerate recovery from Bell's palsy, compared to physical therapy alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 14/11/2013, Comité de bioética en investigación de ciencias de la salud – Facultad de medicina – Universidad Nacional del Nordeste (UNNE), (Moreno 1240, ciudad de Corrientes, Provincia de Corrientes, República Argentina; +54 9 379 4-436057; cbi@med.unne.edu.ar), ref: 30 /17

Study design

Alternate allocation controlled trial

Primary study design

Interventional

Secondary study design

Alternate allocation controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Condition

Bell's palsy

Interventions

Participants are assigned to groups using sequential allocation.

The control condition will receive usual physical therapy, consisting of neuromuscular reeducation and massage therapy. The experimental group will receive selective electrical muscle stimulation, in addition to usual physical therapy. For both groups, treatments are received once daily, Monday through Friday, until they are judged by their treating therapist to

be fully recovered. At enrollment, discharge, and a follow-up visit 6 months after discharge, all participants will be video recorded performing 11 facial expressions. The video-recorded facial movements will be rated by two independent blinded reviewers using the House Brackmann scale and the eFACE scale.

Intervention Type

Device

Phase

Phase II

Drug/device/biological/vaccine name(s)

Electrical stimulation

Primary outcome measure

Static, dynamic, and synkinesis facial function were measured using the eFACE scale at baseline, completion of intervention, and 6 months after completion of intervention.

Secondary outcome measures

Facial function measured on the House Brackmann scale at baseline, completion of intervention, and 6 months after completion of intervention.

Overall study start date

01/02/2017

Overall study end date

31/12/2018

Eligibility

Participant inclusion criteria

- 1. Diagnosis of acute, incomplete Bell's palsy, up to one month from onset of paralysis
- 2. Aged 18 years and above

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

Total final enrolment

Participant exclusion criteria

- 1. Other causes of facial paralysis.
- 2. Hypertension
- 3. Diabetes
- 4. Prior facial physical therapy or muscle stimulation
- 5. Complete facial paralysis

Recruitment start date

01/02/2017

Recruitment end date

01/06/2018

Locations

Countries of recruitment

Argentina

Study participating centre Universidad Nacional del Nordeste

25 de Mayo 868 Corrientes Argentina W3400 BCH

Sponsor information

Organisation

Universidad Nacionale Del Nordeste

Sponsor details

Moreno 1240, ciudad de Corrientes, Provincia de Corrientes, República Argentina.

Corrientes

Argentina

W3400ACY

+54 9 379 4-436057

webmaster@unne.edu.ar

Sponsor type

University/education

Website

www.med.unne.edu.ar

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

01/06/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from tonydipi1@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details in Spanish	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			01/03/2023	No	No
Statistical Analysis Plan			01/03/2023	No	No
<u>Dataset</u>			03/07/2023	No	No
Results article		24/10/2023	08/07/2024	Yes	No