ISRCTN14974687 https://doi.org/10.1186/ISRCTN14974687

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

Submission date
21/02/2023

Recruitment status
No longer recruiting

Registration date
27/02/2023

Overall study status
Completed

Last Edited
08/07/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol

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
Mr Antonio Alejandro Di Pietro

Contact details
Pérez de Herrera 2062
B° Cerro de las rosas
Cordoba
Argentina
X5009 HWD
+54 351 482-5779
tonydipi1@gmail.com

Type(s)
Scientific

Contact name
Dr Villma Campana

ORCID ID
https://orcid.org/0000-0001-6742-8640

Contact details
Pérez de Herrera 2062
B° Cerro de las rosas
Cordoba
Argentina
X5009 HWD
-
vilma.campana@unc.edu.ar

Additional identifiers

Protocol serial number
30/17

Study information

Scientific Title

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

Study objectives
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

Primary study design
Interventional

Study design
Alternate allocation controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
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(s)
Static, dynamic, and synkinesis facial function were measured using the eFACE scale at baseline, completion of intervention, and 6 months after completion of intervention.

Key secondary outcome(s)
Facial function measured on the House Brackmann scale at baseline, completion of intervention, and 6 months after completion of intervention.

Completion date
31/12/2018

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
40

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

Date of first enrolment
01/02/2017

Date of final enrolment
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

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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