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
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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.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
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W3400 BCH

Sponsor information

Organisation
Universidad Nacionale Del Nordeste

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