

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

<b>Submission date</b> 21/02/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/02/2023	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/07/2024	<b>Condition category</b> Nervous System Diseases	<input checked="" type="checkbox"/> 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 Nacional 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

### 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

### **Study design**

Alternate allocation controlled trial

### **Primary study design**

Interventional

### **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?
<a href="#">Results article</a>		24/10/2023	08/07/2024	Yes	No
<a href="#">Dataset</a>			03/07/2023	No	No
<a href="#">Protocol file</a>	in Spanish		01/03/2023	No	No
<a href="#">Statistical Analysis Plan</a>			01/03/2023	No	No