NMES Study Protocol

Identifiers: NCT01999465

Unique Protocol ID: MedSAU-NMES

Brief Title: NMES Efficacy on Patients With NBPP

Official Title: Neuromuscular Electrical Stimulation (NMES) Efficacy on Patients With Neonatal Brachial Plexus Palsy (NBPP)

Version Date: 11/12/2018

Background

Neuromuscular electrical stimulation (NMES) is a common physical/occupational therapy aid utilized for functional recovery in upper or lower limb function following injuries or surgery, yet little documentation exists proving its effectiveness for pediatric patients diagnosed with NBPP. To further the science behind the treatment interventions for patients with NBPP, we propose a study to investigate the effects of NMES on elbow flexion and arm function.

Objectives

The purpose of this study is to investigate whether the use of Neuromuscular Electrical Stimulation (NMES), via the Empi® Continuum unit, will improve the ability with which children with Neonatal Brachial Plexus Palsy (NBPP) are able to use their biceps muscle in activities of daily living. We will examine the British Medical Research Council (MRC) muscle strength and participants' ability to perform active range of motion (AROM) movements. Patients will be divided into two groups with one group receiving NMES and the other receiving sham NMES. We plan to analyze the effects of this one treatment intervention of NMES to determine if the device improves the function of the biceps muscle strength and motion.

Specific Aim and Hypotheses

Aim1. To examine the effectiveness of NMES to improve the function in normal activities involving elbow flexion of the affected arm

> **Hypotheses 1:** Change of biceps MRC strength will be greater in those who receive NMES vs. those receive sham unit from baseline to 3-month (end of study)
>
> **Hypotheses 2:** Change of elbow flexion AROM will be greater in those who receive NMES vs. those receive sham unit from baseline to 3-month (end of study)

Methodology

Inclusion/exclusion criteria

Inclusion Criteria:

- Children ages 3-9 months at time of enrollment
- NBPP patients who receive care from UM Brachial Plexus Palsy clinic
- All gender/race/financial backgrounds
- AROM elbow flexion <150°

- All Narakas grades
- Medical Research Council (MRC) grade 2- or 4 for biceps brachii

Exclusion Criteria:

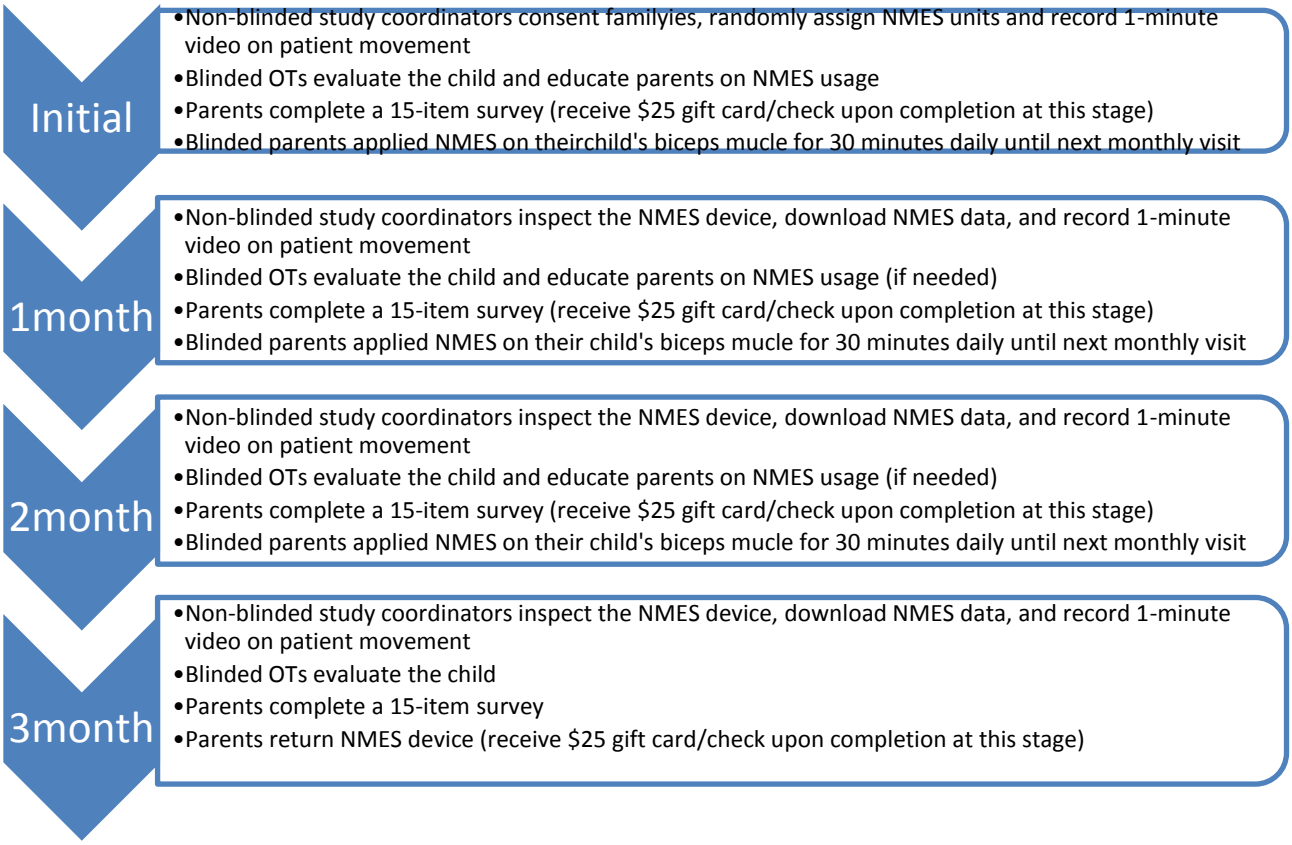
- Brachial Plexus patients require needing surgical repair
- Patients with any existing secondary medical conditions
- Patients with elbow contracture greater than 5°
- MRC grade 5 for biceps brachii
- AROM elbow flexion =150°
- Non-English speaking families
- Children already using NMES unit

Data Collection Procedures

Non-blinded study coordinators will recruit eligible patients. Once the participant's parents complete the consent paperwork, study coordinators will use simple randomization method to assign either active or sham NMES unit to the blinded families. A single coin toss will be used (head-active, tail-sham) to decide the assigned unit. In order to prevent number imbalance during the study, we will monitor the number to make sure there is balance in the number of subjects in each cohort over time. Study coordinators will also record a 1-minute video on patient's spontaneous hand-to-mouth movement.

Parents will then complete a 15-item questionnaire. One of the two-blinded occupational therapists will then complete the initial patient evaluation. Following the completion of the questionnaire and the initial evaluation, the participants' parents will be educated on the proper use of the NMES unit inclusive of home instructions in written, verbal and demonstration format. Follow up visits will be scheduled for 1, 2 and 3 months after the initial evaluation. Between visits, parents will be asked to place the NMES on the biceps muscle of their child for 30 minutes each day.

At each monthly visit, the parents will be asked to bring in the NMES unit to confirm that the device is functioning appropriately and for study coordinators to remove the data from the device that has recorded the amount of time the device had been used since the last visit. The participant's parents will also complete a questionnaire to evaluate for confounders. The participant will also be re-evaluated by the blinded occupational therapist using the initial evaluation parameters. At the initial and each monthly visit, we will record a 1-minute video to collect data on patient's spontaneous hand-to-mouth movement. Upon consent and at each monthly follow up visit, parents will be provided a $25 gift card/check, therefore receiving a $25 of gift card/check for 4 visits = $100 for their completion of the study. The families will return the NMES unit once the study is finished. If parents request a continuation with the treatment device upon study completion a new unit will be ordered for the patient to utilize.



Primary Outcome Measures

One of the two-blinded occupational therapists will conduct the evaluation at enrollment and each follow-up clinic visit. In this study, we will evaluate the biceps strength using the MRC grading system and the active elbow flexion using a goniometer.

1. Biceps MRC Muscle Strength

The MRC grading system for muscle strength is based on a scale from 0 (not testable) to 5 (normal strength). MRC grade 2- or higher is functional in terms of muscle power. In current study, we will examine the change of biceps MRC grade from baseline to 3-month.

2. Elbow flexion AROM

One of the two-blinded occupational therapists will assess the AROM of elbow flexion using goniometer. We will then examine the change of elbow flexion AROM from baseline to 3-month.

Exploratory Outcome Measures

1. One-minute Video Tape

Study coordinators will conduct one-minute video recording with patient in supported sitting position in a chair or seated on parents lap at initial and monthly clinic visits. A toy, pacifier, or bottle will be provided to trigger patient's spontaneous hand-to-mouth movement. The frequency of hand to mouth motion will be recorded and separated out as to the positioning of the elbow. We are evaluating the motion to determine if the motion of the elbow flexion is against gravity, (the arm held at the side of the body or in an adducted position) or in gravity-eliminated position, (the arm held away from the body or in an abducted position). We are looking at the strength of the biceps in its ability to lift the arm against gravity during functional hand to mouth activities. The NMES unit will not be in use during the videotaping process; we are looking at the spontaneous movement of the extremity.

2. 15-item Survey

Parents will complete a survey asking participant's current therapy program, including therapy type, setting, frequency, duration, other treatment activities, splint usage, home range of motion exercise program and its frequency and duration at initial and monthly follow-up visits. The purpose of this survey is to help us understand whether there are potential confounders that could affect the study result.

Intervention (NMES usage at home)

EMPI Continuum unit is a battery-operated machine designed to deliver neuromuscular electrical impulses via sticker type electrodes placed on the skin over a muscle belly with the intention of eliciting a muscle contraction for the purpose of strengthening a muscle and translating that muscle motion into functional activities to increase the patient's skills in preferred activities of daily living.

Blinded parents will follow the NMES parent instructions and place the NMES on the biceps muscle of their child for 30 minutes every day for three months. Parents will bring the NMES device to each monthly follow up visit and the non-blinded study coordinators will check on the proper device usage and download the data from the device. Upon completion of the study at 3 month, parents will return the NMES unit. If parents request a continuation with the treatment device upon study completion a new unit can be ordered for the patient to utilize.

Standard NMES Input Settings:

1. Small Muscle Group
2. Setting (Custom)
3. Off Time (30 Seconds)
4. Rate (35 Hz)

5. Width (300 us)
6. Waveform (symmetrical)
7. Cycling (Simultaneous)
8. Lag (2 seconds)
9. Ch1 Ramp+ (2 seconds)
10. On Time 1 (10 seconds)
11. Ch1 Ramp – (2 seconds)
12. Ch2 Ramp+ (0 seconds)
13. On Time 2 (0 seconds)
14. Ch2 Ramp – (0 seconds)
15. Contrast (28)
16. Languages (English)
17. NMES (locked)
18. TENS (NA)
19. EDEMA (NA)

Sham NMES Unit Settings:

1. Small Muscle Group
2. Setting (Custom)
3. Off Time (60 Seconds)
4. Rate (35 Hz)
5. Width (48 us)
6. Waveform (symmetrical)
7. Cycling (Simultaneous)
8. Lag (0 seconds)
9. Ch1 Ramp+ (0 seconds)
10. On Time 1 (0 seconds)
11. Ch1 Ramp – (0 seconds)
12. Ch2 Ramp+ (0 seconds)
13. On Time 2 (0 seconds)
14. Ch2 Ramp – (0 seconds)
15. Contrast (28)
16. Languages (English)
17. NMES (locked)
18. TENS (NA)
19. EDEMA (NA)

Discontinuation of Participation

A. Parents may decide to discontinue participation in the study for various reasons which may include but not be limited to the following:
   1. Participation is too difficult for any reason including time constraints
   2. Poor tolerance for NMES input
   3. Participant's parent(s) changed their mind
   4. Unforeseen risks occur
   5. Medical situation has occurred that prevents or interferes with ability to participate

B. Study team coordinators may decide to discontinue the participation in the study for various reasons which may include but not be limited to the following:
   1. Misuse of equipment
   2. Unforeseen risks occur
   3. Protocol is not followed
   4. Equipment is not functioning properly
   5. Patient requires surgical intervention to brachial plexus

Study Member Roles

Non-blinded Study Coordinator (Ms. Kate Chang)
Ms. Chang as the non-blinded study coordinator will be in charge of recruiting, consenting, assigning NMES devices, recording 1-minute video, downloading NMES data, administer surveys and distributing gift cards to the families. She will also be involved in de-identified data organization, analysis and manuscript preparation.

Blinded Occupational Therapists (Mrs. Denise Justice, Mrs. Lynnette Rasmussen)
Mrs. Justice and Mrs. Rasmussen will evaluate participated patients' biceps MRC and AROM and educate parents on the NMES usage. They will be blinded on the device type that families receive in order to prevent bias in the study.

Faculty Advisor (Dr. Lynda Yang)
Dr. Yang will be supervising and overlooking the study process. She will also provide suggestions for de-identified data organization, analysis and manuscript preparation. She might have direct contact with participants in the clinic; however, she will be blinded on the patients' study status.

Statistical Analysis Plan

Aim1. To examine the effectiveness of NMES to improve the function in normal activities involving elbow flexion of the affected arm

Hypotheses 1: Change of biceps MRC strength will be greater in those who receive NMES vs. those receive sham unit from baseline to 3-month (end of study)

Hypotheses 2: Change of elbow flexion AROM will be greater in those who receive NMES vs. those receive sham unit from baseline to 3-month (end of study)

Data Analysis Plan:

During the initial and 3-month visits, we will evaluate the participants' biceps MRC and AROM and calculate the changes between baseline and 3-moth follow-up visit using descriptive statistics. Furthermore, allocation assignment (NMES or sham) will be used as the between-subjects factor to compare the differences in biceps MRC score and AROM.