Study Protocol

Official Title: Pilot Study: Hand & foot Neuromodulation for nocturnal enuresis in children

ClinicalTrials.gov ID (NCT number): NCT02747849

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Scientific Background

Nocturnal enuresis is a common problem in children which can have a dramatic psychological and social impact on quality of life. Neuromodulation by transcutaneous foot stimulation of peripheral tibial nerve branches has been shown to produce a prolonged inhibition of micturition reflex contractions and significantly increase bladder capacity. Our primary goal was to evaluate the effect of foot stimulation on the frequency of nocturnal enuresis episodes in children.

Study Objectives

We believe in order to strengthen the evidence in support of transcutaneous foot stimulation in this population we need to move forward with a randomized comparison study using the TENS device on the hand and foot as a control. The goal of this study is to prove that hand stimulation with the TENS device will not decrease nocturnal enuresis in children and will serve as a placebo 2) to prove that stimulation to the foot with the TENS device does decreasing the nocturnal enuresis in children.

The goal of this study is to prove that hand stimulation with the TENS device will not decrease nocturnal enuresis in children and prove that stimulation to the foot with the TENS device does decreasing the nocturnal enuresis in children.

Study Design & Methods

This is an experimental, randomized study. Both the subject and the investigator will be informed about the foot and hand stimulation. The results obtained will be compared between the two groups. The study is expected to end when the six weeks have been completed with associated completion of weekly night-time voiding log and quality of life questionnaires. However, if the subject cannot follow the study procedures such as an inability to tolerate foot or hand stimulation or non-compliance with completing night-time voiding logs and/or quality of life questionnaires, the subject's participation will be discontinued and the study will be ended. We expect some electrodes to detach from the foot or hand. However, occasional unattached electrodes will not end the study, since the data will be collected in a week period and a few occurrences of detachment should not change the results. Also, if skin irritation is caused by the electrodes, the study will continue by using the other foot or hand and giving the irritated foot or hand a day or two to recover. However, if unexpected serious irritation occurs that cannot be avoided by changing feet or hands, the study will be terminated for that subject

Eligibility Criteria

Inclusion Criteria- The subject population age range is 5 to 18 years of age. The child needs to be adequately potty trained with daytime dryness and be able to communicate quality of life subjective information to parents. Children who are unable to communicate quality of life subjective information to parents effectively will not be included in this study.

Exclusion Criteria- Child outside the age range or unable to communicate effectively, not adequately potty trained without daytime dryness.

Statistical Considerations

The data will be statistically analyzed using student t-test and ANOVA.