RESEARCH STUDY
For patients with cerebral palsy

Effect of Botox® and vibration on bone in children with cerebral palsy

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of the study is to examine the effects of Botox muscle injections on bone and muscle in children with cerebral palsy (CP) and to determine if standing on a vibration platform for 10 minutes a day during the months after Botox treatment will improve bone health. We also want to examine the influence of Botox treatment on physical activity.

WHAT WILL HAPPEN DURING THE STUDY?

Both the children who receive Botox treatment and the children whose families have declined Botox treatment will undergo a number of measurements of bone and muscle health. These measurements will be taken at two or three time points:

1. At the beginning of the study (before Botox treatment)
2. One month after Botox (only for children who received injections)
3. Seven months after beginning the study

The study will last approximately seven months. It will involve seven test sessions. Each session will last between 1 and 2 ½ hours.

The measurements for this study include:

- physical examinations
- blood and urine tests
- a bone scan (to examine strength properties of the leg bones)
- an MRI scan (to examine bone size, and amount of muscle and fat in the legs)

Some measurements will be performed at the Nemours/Alfred I. duPont Hospital for Children and some measurements will be performed at the University of Delaware.

As part of this study, some children will be asked to stand on a vibration box for 10 minutes each day at home while in the study. The researchers will provide and demonstrate use of the box. The box shakes a very little bit, so little that some children cannot feel the shaking.

WHO CAN PARTICIPATE?

If you meet the following criteria:
1. Have spastic CP.
2. Are between 2 and 12 years of age.
3. Have not had Botox treatment in the lower extremities within the past one year.
4. Botox has been presented as a treatment option by your physician as part of your clinical care.
5. Earned a score of 1-4 on the gross motor function classification system (GMFCS).
6. Do not have metal rods in the mid thigh or leg.

FOR MORE INFORMATION, PLEASE CONTACT:

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