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Vibration Intervention to Improve Bone and Muscle in Children With Cerebral Palsy

This study has been completed.

First Received: February 21, 2006 Last Updated: December 14, 2007 [History of Changes](#)

Sponsor:	National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Information provided by:	National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
ClinicalTrials.gov Identifier:	NCT00295295

Purpose

Cerebral palsy is a group of disorders characterized by lack of coordination in the muscles, loss of movement, and speech disturbances. These disorders are caused by injuries to the brain that occur during fetal development or near the time of birth. The purpose of this study is to determine the effects of high frequency, low magnitude vibration on bone and muscle in children with cerebral palsy.

Condition	Intervention	Phase
Cerebral Palsy	Procedure: High frequency, low magnitude vibration	Phase II

Study Type: Interventional
 Study Design: Allocation: Randomized
 Control: Active Control
 Endpoint Classification: Efficacy Study
 Intervention Model: Crossover Assignment
 Masking: Open Label
 Primary Purpose: Treatment

Official Title: Mechanical Intervention in Children With Cerebral Palsy

Resource links provided by NLM:

[MedlinePlus](#) related topics: [Cerebral Palsy](#) [Paralysis](#)

[U.S. FDA Resources](#)

Further study details as provided by National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS):

Primary Outcome Measures:

- Vertebral bone density [Time Frame: Measured at Month 12] [Designated as safety issue: No]
- Tibia bone density [Time Frame: Measured at Month 12] [Designated as safety issue: No]
- Tibia cross-sectional area [Time Frame: Measured at Month 12] [Designated as safety issue: No]

Secondary Outcome Measures:

- Calf muscle strength [Time Frame: Measured at Month 12] [Designated as safety issue: No]
- Balance test [Time Frame: Measured at Month 12] [Designated as safety issue: No]

Estimated Enrollment: 34
 Study Start Date: September 2004
 Study Completion Date: September 2007

Detailed Description:

The extent of bone mass built up during childhood and adolescence is the most important determinant of osteoporosis later in life. Some disabled children, such as those with cerebral palsy, are particularly vulnerable to low bone mass accumulation due to decreased mobility and weight-bearing. These children also have poor muscle strength and control, which limits function and contributes to the lack of mechanical stimulation needed to build bone mass. The most common treatment for these children is physical therapy, which is time- and labor-intensive and may not be adequately available to them. Whole body vibration has shown promise as an alternative method for stimulating increases in bone mass and improvements in muscle. The purpose of this study is to evaluate the effects of high frequency, low magnitude vibration on bone and muscle in children with cerebral palsy. This intervention may be useful as a noninvasive, nonpharmacological treatment for low bone mass and poor muscle function in these children.

This study will last 1 year. All participants will visit the hospital 3 times, at study entry and Months 6 and 12. At each visit, height and weight will be measured, muscle strength and balance will be tested, and bones and muscles in the spine and lower leg will be imaged with computed tomography (CT), a special x-ray machine. Participants will be randomly assigned to one of two groups. For this study, all participants will be asked to stand for 10 minutes every day for 1 year. For Group 1, a vibrating platform will be used for the 10-minute standing sessions during the first half of the study but not during the second half of the study. For Group 2, this will be reversed and the vibrating platform will not be used during the first half of the study but will be used during the second half of the study.

Eligibility

Ages Eligible for Study: 6 Years to 12 Years
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Diagnosis of cerebral palsy
- Low vertebral bone density
- Able to stand for 10 minutes with handheld support
- Parent or guardian willing to provide informed consent

Exclusion Criteria:

- Surgery, casting, or receipt of botulinum toxin in the 12 months prior to study entry
- Planned surgery, casting, or receipt of botulinum toxin in the 12 months after study entry
- Metal rods or plates in tibia or lumbar spine
- Severe scoliosis (greater than 20 degrees) or bowing of tibia
- Medical condition other than cerebral palsy affecting bone or muscle
- Require corticosteroids or seizure medication (phenytoin)

▶ Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00295295

Locations**United States, California**

Childrens Hospital, Los Angeles
Los Angeles, California, United States, 90027

Sponsors and Collaborators

[National Institute of Arthritis and Musculoskeletal and Skin Diseases \(NIAMS\)](#)

Investigators

Principal Investigator: Tishya A.L. Wren, PhD Childrens Orthopaedic Center, Childrens Hospital Los Angeles, and Departments of Orthopaedics and Radiology, Keck School of Medicine, Depart

▶ More Information

No publications provided

Study ID Numbers: 1-R21-AR051564, 1-R21-AR051564
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Health Authority: United States: Federal Government

Keywords provided by National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS):
vibration
bone density

Additional relevant MeSH terms:

Cerebral Palsy
Nervous System Diseases
Brain Damage, Chronic
Central Nervous System Diseases
Brain Diseases

ClinicalTrials.gov processed this record on April 26, 2010

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