

**Clinical Trial ID:**

**NCT00000415**

**Title:**

**Physical Activity, Calcium, and Bone in Children**

**Summary:**

**Doctors recommend that young children participate in daily physical activity to promote**

**bone health. However, studies in adults show that physical activity and increased calcium**

**intake cause noticeable benefits for bone health only when both factors occur together.**

**The goal of this study is to find out whether calcium intake changes the response of bone**

**to activity in children 3 to 4 years old. Children will participate in one of two programs conducted in childcare centers 5 days a week for 1 year. One program will**

**involve activities that use large muscles (gross motor activity). The other will involve**

**activities using small muscles (fine motor activity). We will give a calcium supplement**

**(1 gram per day) to half of the children in each program and give the other half an**

**inactive pill. We will measure bone mass and bone mineral density at the beginning and**

**end of the study. We will take measurements 12 months after the program's**

**completion to**

**see if physical activity and/or calcium supplements have long-term effects on bone**

**mineral density and physical activity.**

**Detailed Description:**

**Participation in daily physical activity programs by young children is currently recommended as a means of promoting bone health. Results from studies of adults indicate**

**that beneficial effects of either physical activity or calcium (Ca) intake may be apparent only when both these factors are present. Our results in infants indicate that**

**physical activity combined with a low Ca diet may be detrimental in terms of bone mass**

**accretion. The overall objective of this study is to determine whether Ca intake modifies**

**the bone response to activity in young children 3 to 4 years of age.**

**Our hypotheses are that (1) the increase in bone mass resulting from a physical activity**

**program will be more pronounced in children randomized to receive a Ca supplement**

**compared to the increase in children randomized to receive a placebo; and (2) 12 months**

**after cessation of the activity program, bone mass will remain higher in children**

**randomized to gross motor activity compared to children randomized to fine**

**motor**

**activity, and the beneficial effect of Ca supplementation will persist only among**

**children randomized to gross motor activity. We will test these hypotheses in a**

**randomized 2 x 2 factorial trial in 3- to 4-year-old children. We will randomize children**

**into either a gross motor or fine motor activity program that will be conducted in**

**childcare centers 5 days a week for 1 year. We will further randomize each child into**

**either a Ca supplement (1 g/d) or placebo group.**

**The primary outcomes of the study are bone mass accretion and changes in bone mineral**

**density, which we will determine by dual energy x-ray absorptiometry at the beginning and**

**end of the study. We will do activity assessments throughout the study period to**

**determine whether participation in the gross motor activity group also increases**

**spontaneous activity in these children. Anthropometric measurements and dietary**

**information will allow us to statistically control for these potential confounders. We**

**will obtain additional bone mass and physical activity measurements 12**

**months after**

**completion of the program to determine if these interventions have long-term effects on**

**bone mineral density and physical activity.**

**A finding of beneficial effects of Ca supplementation or physical activity, either**

**independent of each other or in combination, will lay the groundwork for devising**

**prevention strategies within the educational system that optimize bone health beginning**

**early in life. However, we may find that increased physical activity in the presence of a**

**low to moderate Ca intake may have a detrimental effect on bone mass accretion during**

**periods of rapid growth.**

**Eligibility Criteria:**

**Inclusion Criteria:**

- Enrolled in participating childcare center.**
- Does not plan to attend kindergarten or withdraw from center in the next 12 months.**

**Exclusion Criteria:**

- Chronic disease that may interfere with growth and bone mass accretion (cystic fibrosis, liver disease, asthma that is being treated with steroids, juvenile rheumatoid arthritis, immobilization).

**Gender:**

**All**

**Minimum Age:**

**3 Years**

**Maximum Age:**

**4 Years**

**Phase:**

**Phase 2**

**Conditions:**

- Physical Activity
- Nutrition

**Interventions:**

- Physical activity
- Calcium supplement

**Locations:**

- South Dakota State University, Brookings, South Dakota