Clinical Trial ID:

NCT00000402

Title:

Calcium and Bone Mass in Young Females

Summary:

We originally suggested that calcium in the diet is important in determining the amount of bone (bone mass) that builds up in young adults. We are testing the effect of calcium on bone mass in 354 Caucasian (white) girls. At the start of this 7-year study, the average age of the girls was 11 years, and they had not yet reached puberty. The study will also provide information about the effect of calcium on body composition (body fat) and blood pressure in young women.

We have been giving calcium to one group of participants in this study and giving a placebo (an inactive pill, or "sugar pill") to the other group. The results of this research will be important in preventing osteoporosis, because building more bone as a young person should reduce a woman's chances of developing osteoporosis later in life.

Detailed Description:

This study evaluates the effect of calcium on bone mass accretion over 7 years in a cohort of 354 young females who were in pubertal Stage II at the start of the study. The average age of study participants at entry was 11 years; at the end of the study participants were 18 years old.

The study looks at skeletal development under the influence of heredity, nutrition (calcium), and physical exercise. We gave calcium to participants in one arm of this clinical trial calcium. Participants in the other arm of the trial were given a placebo.
The main outcome variable is the bone mass measured at different skeletal regions.

The study will also provide data about the efficacy of calcium supplementation with regard to hypertension prevention and obesity. The results of this research will be important in preventing osteoporosis.

Eligibility Criteria:

Inclusion Criteria:

- **Pubertal stage II**

- **Calcium intake below a threshold level**

- **Caucasian**

- **Normal health**

Exclusion Criteria:

- **Medications affecting calcium and bone metabolism**

- **Chronic diseases**

- **Metabolic bone disease**

- **Abnormality in calcium metabolism**

Gender:

Female

Minimum Age:

8 Years

Maximum Age:

13 Years

Phase:

Phase 2

Conditions:

- Osteoporosis

Interventions:

- Calcium

Locations:

- OSU Bone and Mineral Metabolism Laboratory, Columbus, Ohio