Clinical Trial ID:

NCT00000412

Title:

Osteoporosis Prevention After Heart Transplant

Summary:

During the first year after a heart transplant, people often rapidly lose bone from their spine and hips. About 35 percent of people who receive heart transplants will suffer broken bones during the first year after transplantation. This study will compare the safety and effectiveness of the drug alendronate (Fosamax) and the active form of vitamin D (calcitriol) in preventing bone loss at the spine and hip after a heart transplant.

In this study, people who have had a successful heart transplant will receive either active alendronate and a "dummy pill" instead of calcitriol, or active calcitriol and a dummy pill instead of alendronate for the first year after their transplant, starting within 1 month after transplant surgery. We will measure bone density in the hip and spine at the start of the study and after 6 and 12 months, and will also check

for broken

bones in the spine. This research should lead to ways of preventing this crippling form

of osteoporosis.

Detailed Description:

We will enroll patients who have undergone cardiac transplantation into a randomized,

double-blind, 12-month study of the efficacy and safety of calcitriol (Rocaltrol) and

alendronate sodium (Fosamax) in the prevention of bone loss after transplantation. We

will give all participants standard pre- and post-transplantation management and

immunosuppressive therapy, three tablets of calcium citrate (Citracal + D, each

containing 315 mg of elemental calcium and 200 IU of vitamin D), and a multivitamin

providing 400 units of vitamin D daily. We will randomize participants to one of two

active treatment groups within 1 month of transplantation. We will give Group A active

alendronate (10 mg/day) and placebo calcitriol. We will give Group B placebo alendronate

and active calcitriol (0.25 micrograms BID). The primary efficacy endpoint is the change

in spine bone mineral density (BMD) during the first 6 months after

transplantation. The

secondary efficacy endpoint is the change in hip BMD during the first year after

transplantation. We will also monitor the incidence of vertebral fracture.

We will invite eligible subjects to participate in the study. We will offer patients who

elect not to participate in the therapeutic trial the opportunity to have serial BMD

measurements at the same intervals as treated subjects and to be followed as untreated

controls. We will continue recruitment until we have randomized a total of 146 cardiac

transplant recipients. We will perform bone densitometry at randomization (unless

performed within the previous month) and at 6 and 12 months. We will obtain radiographs

(x-rays) at randomization and will repeat them at 12 months to detect undiagnosed

vertebral fractures.

Eligibility Criteria:

Inclusion Criteria:

- **Cardiac transplantation**

Exclusion Criteria:

- **Active peptic ulcer disease, gastrectomy, inflammatory bowel disease, malignancy,**

Paget's disease of bone, osteogenesis imperfecta, multiple myeloma, primary

hyperparathyroidism, rheumatoid arthritis, Cushing's syndrome, or thyrotoxicosis

- **Suppressive doses of thyroid hormone, anticonvulsant drugs, past bisphosphonate**

therapy, current calcitonin therapy, or fluoride therapy

- **Cirrhosis, inflammatory liver disease, or nephrolithiasis**

- **Serum creatinine > 2.5 mg/dl**

Gender:

All

Minimum Age:

20 Years

Maximum Age:

70 Years

Phase:

Phase 3

Conditions:

- Osteoporosis

- Cardiac Transplantation

Interventions:

- Alendronate

- Calcitriol

- Placebo Alendronate

- Placebo Calcitriol

Locations:

- Columbai University Medical Center, New York, New York

- Columbia University Medical Center, New York, New York