

The Incidence Of Osteoporosis In African American Men Over 50 Years Age

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A. Study Purpose and rationale

Men account for one third of the 1.7 million hip fractures worldwide with a higher mortality rate than women. Approximately 2 million American men have osteoporosis and another 3 million are at risk for the condition(1). Osteoporosis results in longer hospital stays than several common diseases of the elderly including, myocardial infarction, diabetes mellitus, bronchitis, emphysema, and asthma. With an increasing age specific incidence rate and increased elderly population, osteoporosis is a major public health problem (2).

No recent studies have investigated the incidence of vertebral or hip fractures in African Americans. Often cited data regarding the incidence of osteoporosis in this population is from a 1960's study of elderly African Americans and whites noted the incidence of compression fractures to be 17 and 24%, respectively. Many studies have cited the higher bone densities of African Americans but none investigate the actual incidence of the disease. Given that African American men suffer from many risk factors for osteoporosis (i.e. alcohol, smoking, medications, chronic kidney and lung disease, etc.) it remains an area inadequately researched. Our goal is to provide an estimate of the incidence of this largely undiagnosed and under reported condition and thus an estimate of its public health significance. (4,5,6).

B. Study design and statistical analysis

Prospective cohort study recruiting African American male residents of Northern Manhattan (designated by zip code). For a routine physical exam and osteoporosis screening for a maximum of two years or until adequate recruitment has been established. Recruitment representation will be evaluated against census data regarding geographic distribution, age , and socioeconomic data.

C. Study Procedures

A physical exam including prevention screening, measurement of bone mineral density at the ultra distal radius and mid shaft radius via the portable single photon absorptiometry and hip and spine via the portable dual energy x-ray absorptiometry.

D. Study Drugs

none

E. Medical Devices

Newly developed portable single photon absorptiometry scan(PAS) Model xxx and portable x-ray absorptiometry (XA) Model x 18 provided courtesy of Luluray machines incorporated, Waco, Texas to all facilities. FDA approved studies demonstrated precision errors of approximately .5% for both models.

F. Study Questionnaires

Study questionnaires will evaluate health habits, medical history, dietary supplements, medications (names, doses and routes of administration) as verified by nursing staff at time of physical exam, history of falls or trauma, alcohol use, as well as calcium intake of participants. All data except questionnaire and medicine verification will be gathered by primary care physicians. The remainder of the data will be gathered by registered nurses certified in the use of the PAS model xxx and XA model x 18.

G. Study Subjects

African American men over age 50 years for reasons outlined in study purpose.

H. Recruitment of Subjects

Patients will be recruited from the Northern Manhattan area (Central Harlem and above) via local employers, churches, schools, local health fairs, flyers and print advertising in community papers. Letters of support for the study have been received from local the community board, Harlem Council of Churches, local democratic clubs, and community service organizations. Members have volunteered their services for recruitment efforts (see attached).

I. Confidentiality of Study

Data Each study subject will be given a code number. All study data will be coded without any identifying information stored securely in the ICCR security lockers accessible only to the principal investigator and ICCR statistical evaluation team (SET).

J. Potential Conflict of Interest

none

K. Location of the study

Columbia University Medial Center and its affiliate institutions located in Northern Manhattan including: Milstein, Allen Pavilion, ACNC clinics, St. Luke's and Harlem Hospital. Each institution's administrative director, IRB outpatient clinical and administrative director, and nursing coordinator approved study participation in writing (see attached).

L. Potential Risks

Other than the routine discomfort of a physical exam and portable x-rays. This study is of little risk to participants. Although the levels of radiation used in this study are within federal guidelines for research of this type, radiation risk is cumulative over a lifetime, so any additional exposure should be carefully considered.

M. Potential Benefits

As a result of participation in this study patients will obtain physical exam including prevention screening/ follow up and establish a relationship with a primary care physician. N. Alternative Therapies Given this is a non therapeutic study the alternative is to not participate.

N. Compensation to Subjects

none

O. Costs to Subjects

Local transport to and from primary care physician - no additional costs should be incurred by subject secondary to protocol participation. Bone mineral density screening and routine physical exam cost are at no charge to participant. Luluray machines inc. will reimburse each institution for bone screening and physical exam.

P. Minors as Research Subjects

not applicable

Q. Radiation or radioactive substances

All bone screening will be conducted as per Joint Radiation Safety Committee. A separate application for JRSC approval has been submitted.

R. References

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3. Moldawer M, Zimmerman SJ and Collins LC. Incidence of Osteoporosis in Elderly Whites and Elderly Negroes. JAMA 1965; 194(8):859-862.
4. Tenover, Joyce S. Effects of Testosterone Supplementation in the Aging Male. Journal of Clinical Endocrinology and Metabolism. 1992; 75(4): 1092-1098.
5. Wright NM, Renault J, Willi S et al. Greater Secretion of growth hormone in black men than in white men: possible factor in greater bone mineral density. 1995; (80:2291-2297
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