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TITLE: Efficacy of Calcium and Vitamin D Supplementation for the
Prevention of Stress Fractures in Female Naval Recruits

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13. ABSTRACT (Maximum 200 Words) The goal of this project is to determine if calcium and vitamin D intervention can reduce the incidence of stress fracture by at least 50% in female Naval recruits during basic training. We will recruit 5200 recruits who will be randomly assigned to an intervention group given calcium 2000 mg and vitamin D 800 I.U. per day or a control placebo group. The recruit intervention and stress fracture monitoring will continue through 8 weeks of basic training. Positive findings from this study would provide support for the Navy to adopt an easy, low cost method of further decreasing incidence of stress fractures. We experienced a smooth study start up and successful recruitment until the project was placed on hold from Oct. 14, 2002 until Sept. 18, 2003 by the IRB at the Great Lakes Naval Hospital. Our understanding is that all clinical studies were temporarily stopped while the IRB structure was revamped. We restarted in September 2003 with new study personnel, and the project is running very well. To date, we have enrolled 1321 female recruits into the study, 477 since September 2003. We are retaining about 94% of enrolled participants. We have no findings to date.				
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Annual Report for Period of October 1, 2002- September 30, 2003

Project title: Efficacy of calcium and vitamin D supplementation for the prevention of stress fractures in female Naval recruits

Introduction

Stress fractures during military basic training remain a major concern despite training modifications that have decreased stress fracture incidence. Stress fractures are especially prominent in women. These injuries result in loss of manpower and high medical expense, occasionally incurring service-related disability. Supplementing female recruits with calcium and vitamin D may supply nutrients needed to meet training demands and thereby significantly reduce risk of fracture. Inadequate calcium and vitamin D intake may limit bone adaptation since recruits under 30 years of age have not achieved peak bone mass, training stimulates bone formation and micro-fracture repair, calcium intakes are normally low, and substantial dermal calcium losses occur during training. The goal of this project is to determine if calcium and vitamin D intervention can reduce the incidence of stress fracture by at least 50% in female Naval recruits during basic training. We will recruit 5200 recruits who will be randomly assigned to an intervention group given calcium 2000 mg and vitamin D 800 I.U. per day or a control placebo group. The recruit intervention and stress fracture monitoring will continue through 8 weeks of basic training. Positive findings from this study would provide support for the Navy to adopt an easy, low cost method of further decreasing incidence of stress fractures.

Body

Research accomplishments associated with each task outlined in the approved Statement of Work are outlined in Table 1. After receiving notification of funding, we worked with the DOD regulatory persons and our institutional review board as quickly as possible to obtain approval for starting the study. We did not receive final approval from the DOD until April 2004. We started recruitment one month later. We were actively recruiting until September 26, 2002 when we were notified by the Great Lakes IRB that we were to stop recruitment and put the study on hold. We understand that all active clinical projects were stopped at the Great Lakes at that time. We were allowed to complete follow up of enrolled subjects.

Table 1. Research Accomplishments Associated with Tasks in the Statement of Work

	Original	Actual/Projected	Explanation of discrepancies
Planning and set up	7/01-12/01	9/01-5/02	Although the project was funded 9/01, the DOD did not approve us to start until 4/02. We started one month after approval.
Enrollment, intervention and data collection	1/01 - 12/03	5/02 - 1/05	About 4.5 months after startup, enrollment was put on hold by the Great Lakes IRB for about 10 months.
Data clean up and analysis	1/04-6/04	2/05 - 7/05	Delayed as described above

While being on hold, we were assigned to a different IRB from our initial one at the Great Lakes, and we worked with them to obtain approval. We received that approval on August 7, 2003 and restarted recruitment on September 18, 2003. During the time we were on hold, our two project staff members resigned. We have replaced them with two new staff persons. The project manager, Ms. Renee Ahlfs, has considerable experience working with Navy research projects at the Great Lakes and is definitely an asset to this project.

To date we have enrolled 1321 study participants. We have enrolled 477 of those participants since we restarted recruitment on September 18, 2003. We have excellent retention with only 85 drops (6% of those enrolled) from study. Of the 85 drops, 41 were discharged from the Navy or transferred to a Navy unit that was not involved in the study.

The mean age of the study participants is 19.9 (± 2.6) years. The ethnic/racial breakdown is as follows: American Indian/Alaskan 2.49%; Asian 4.51%; Black/non-Hispanic 15.18%; Hispanic or Latino 13.64%; White/non-Hispanic 58.01%.

Key Research Accomplishments

- Implementation of a project that does not interfere with the flow of Naval basic training
- Prompt restart of the project after approval, including hiring and training of new study personnel
- Retention of 94% of enrolled subjects

Reportable Outcomes

No reportable outcomes at this time.

Conclusions

We are drawing no conclusions at this time since we have not completed the study.

References

None

Appendices

None