

HORMONE STUDY and 30 WEEKS OF WALKING:

What exactly will be done to me, and what kinds of treatments or procedures will I receive, if I agree to be a research subject in this study?

This study will involve a walking program at different walking speeds for a period of 30 weeks. We will first determine your body fat and aerobic fitness. Body fat will be assessed by measuring skinfold thickness and circumference of different parts of your body. This will be done in the CCRB and take approximately 30 minutes. Body fat will be also measured through a whole body with a very low-radiation dose X-ray scan called DEXA. This will be done at the School of Public Health and take about 45 minutes. We will also measure total body fat by bioimpedance in the General Clinical Research Center (GCRC). This is done by measuring your body water with a very weak electric current. These procedures will allow us to accurately determine how much fat there is in your body, where it is distributed, and how it changes with exercise training. Your aerobic fitness will be assessed by having you breathe through a mouth piece as you walk on a treadmill at different speeds. We will be measuring your aerobic capacity from the breathing rate and the amount of oxygen you consume as the effort increases. On the basis of the body fat and aerobic fitness, we will match you with two other women of similar body composition and aerobic capacity and assign you to a slow or fast-walking group. Walking will be carried out five days a week. You will start with one mile per day, and increase distance by one half mile each week until you attain 3/miles per day. You will keep walking 3 miles/day five days a week until the end of week 30. The same measurements (aerobic capacity and body composition) will be repeated after 15 and 30 weeks of training.

The study also involves blood collection on three occasions, at the start of the study and after 15 and 30 weeks of training. The first and second time, you will be admitted to the General Clinical Research Center (GCRC) for a total of 17 hours, and the third time for a total of 14 hours. Upon admission by 5 pm, an intravenous cannula will be placed in an arm vein or removal of blood samples and for injection of hormone insulin and sugar glucose. A blood sample (2 ml) will be collected at 10-minute intervals between 6 pm and 8 am the next morning. Dinner will be served at 6 pm, and a snack at 9 pm. On two occasions only (at the start and after 15 weeks), you will be given no food by mouth from when you wake up in the morning until 12:00 noon. At 08:00 in the morning a second catheter will be inserted into a hand vein and you will receive some glucose through the other catheter. On those two occasions, between 8 am and 12:00 h, hormone insulin and glucose will be given through one catheter and blood samples will be taken at frequent (1 minute to 10 minute) intervals through the other to see how rapidly your body takes up glucose from the blood. This tells us how sensitive your body is to hormone insulin and indicates the risk of your becoming diabetic. About one half of a pint of blood will be removed during two tests which is about one half of the amount that can be safely removed at any one time.

We will also ask that you fill out three-day dietary recalls and 7-day activity questionnaires on three occasions, at the start of the study, after week 15 and week 30 of walking. This will take about 10 minutes for each form each time. From this we will determine how many calories you eat and from which food groups and how much energy you expend in sleep and different physical activities.

We will share with you all the health information we obtain through measurements. All of your records will be kept confidential.

COMPENSATION: \$150 upon completion of the study.