

# Information Sheet for Participants

## What is the study about?

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Osteoporosis is a condition in which bones become weak and break easily. Fractures in later life from osteoporosis are common, costly and cause significant death and disability. They may be reduced by improving the amount of bone laid down in childhood and adolescence, so finding out how to make sure that the greatest amount of bone possible is developed is very important.

### **Vitamin D and bone development**

Vitamin D is a substance which acts in the body to regulate how much calcium is put into bone. In Australia, most vitamin D comes from our skin manufacturing vitamin D with sun exposure, though some foods also contain vitamin D, such as fatty fish. Vitamin D deficiency is diagnosed by a simple blood test. Childhood vitamin D deficiency is common and is harmful for bone development. We need to know if using vitamin D supplements in children and adolescents can improve bone health.

This study aims to determine what effect vitamin D supplements have on bone development in adolescents who have mild to moderate vitamin deficiency.

## Who is being asked to participate?

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We will be studying up to 660 healthy adolescents (aged between 15-17) from schools in the Hobart region over a two year period. Participants will be chosen from a number of different schools throughout Hobart. The Principals and appropriate Education Departments have given permission for this study.

Participants can be included in the study if they have mild to moderate vitamin D deficiency. Recruitment will occur between July and October 2008.

## How long will the study go for and what will it involve?

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Initially, your son/daughter will be asked to attend a screening visit, where blood will be taken to test vitamin D levels and a few simple questions asked about their health.

If your son/daughter has normal vitamin D levels, they will not be asked to continue the study, and they will be given a copy of their vitamin D result.

If your son or daughter has mild to moderate vitamin D deficiency, we would like them to continue in the study.

If they have severe vitamin D deficiency, they will not be asked to continue in the study, and we suggest that they see their GP. We will give them a copy of their results and some information to take to their GP.

If your child has any of the following conditions, they will not be asked to continue the study:

- Known severe kidney problems
- Malabsorption
- Pregnancy or breastfeeding
- Rickets

### **Continuing in the Study**

The study will go for two years as the effects of vitamin D on bone take this long to be measured adequately. If your son/daughter continues in the study, we will need to see them at baseline, briefly at 2 weeks and three months, and then at six months and 6 monthly for 3 more visits.

The visits at two weeks and three months involves only taking a small blood sample to check calcium, phosphate and kidney function and will take only a few minutes. Where possible, we will perform these at your son/daughter's school.

The other visits utilise a comprehensive protocol which takes about 1 hour. Measures will be done at the Menzies Research Institute. We can arrange transport for your son/daughter from school to the Menzies Research Institute and back, or you may wish to make your own arrangements. Details are provided on the 'Transport Consent Form'.

At the baseline and six monthly appointments the following measures will be made:

- A questionnaire (including questions about fractures family history of osteoporosis and / or fracture, sunlight exposure, smoking, diet and socioeconomic factors).
- Measurement of height, weight and body mass index.
- Self-assessment of physical maturity using Tanner stage drawings. These are etchings indicating degree of pubic hair. The participant is asked to decide which etching best reflects their current stage.
- Measurement of static and dynamic balance, including balancing on two boards, jumping and clapping, and walking backwards.
- Collection of an early morning urine sample to measure markers of bone resorption
- Measurement of heel bone density using Sahara Clinical Bone Sonometer. This is non-invasive and only takes a few minutes to perform.
- Measurement of physical activity using an accelerometer – a small electronic device (similar to a pedometer) which measures the amount of movement that your son/daughter makes during the day. Your son/daughter will be asked to wear an accelerometer for 7 days and to fill out a diary showing the times they were wearing it.
- Measurement of muscle strength by dynamometry in the lower limb and hand.
- A small (9 ml) amount of blood will be taken will be taken to look at Vitamin D levels and bone formation markers
- Permission will also be sought to access medical records to confirm fracture events if your son/daughter has a fracture during the course of the study.

At baseline and six monthly thereafter you will be given 6 vitamin D supplement or placebo tablets. Placebo tablets do not contain any active ingredients. There are three arms of medication that you could receive:

- Six placebo tablets (no vitamin D)
- Three placebo and three vitamin D tablets (containing a total of 150,000 international units of vitamin D)
- Six vitamin D tablets (containing a total of 300,000 international units, of vitamin D).

As this is a blinded trial individuals will be unaware of which type of tablets they have received until we have completed all data collection for the entire study.

## **Bone Density Scan**

At baseline, one year and two years we will measure bone density by bone



densitometry (also known as DXA) at the spine, hip and total body.

This is a simple, painless procedure which takes approximately 20 minutes and is performed by a radiographer at the Menzies Research Institute. This can be done at any time during the week. Participants lie on a table while a scanner passes above them. This measure involves a small amount of radiation exposure. The exact amount is 0.01mSv which is well under, in fact 50 times less than the recommended maximum level of 0.5mSv per year for research participants under the age of 18 years. It is equivalent to one day's background radiation from natural sources and much less than is involved in a test like a chest x-ray. This level of exposure is unlikely to be associated with any increased risk of disease.

## **Are there any possible risks or discomforts?**

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As mentioned above bone densitometry involves a small exposure to radiation. This is unlikely to be associated with an increased risk of disease based on current evidence.

Collection of blood samples is done by a qualified venepuncturist. This causes minimal risk, but there may be a slight chance of bruising afterwards. If you have needle phobias or problems with blood collection we are able to provide emla (anaesthetic) patches to be applied to the blood taking site half an hour before the sample is collected. We endeavour to make the collection process as simple and as stress free as possible.

The doses of vitamin D we will use during the study are safe. The highest dose we give is less than half of the Australian upper level of intake considered safe for 14 to 18 year olds. Similar doses have been used in other studies in children and no significant side effects were seen. Any side effects are therefore unlikely.

Rarely, a person may have increased calcium level in their blood from this dose of vitamin D. For this reason, we ask that you do not take any calcium supplement tablets during the trial. We will check that your blood calcium levels are satisfactory 2 weeks and again 3 months after your first dose of tablets. In addition, should you experience symptoms such as nausea, vomiting, constipation, loss of appetite, apathy, headache, thirst, sweating or increased production of urine, we ask that you notify us in case your calcium levels need checking.

Other side effects are unlikely unless you have significant kidney problems, but these include deposits of calcium occurring in the kidneys or blood vessels. If you have known kidney problems, you will be excluded from the study.

## **Do I have to participate?**

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Participation is entirely voluntary and subjects who decide to take part in the study can withdraw (including their data) at any time without effect.

## **Will I receive any feedback or results?**

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Feedback will be provided on the overall study results when they are available. Individual results from the bone density scans and other tests will also be made available at the end of the study or if clinically necessary eg after a fracture.

If you are excluded from the study because of normal vitamin D levels or alternatively due to severe vitamin D deficiency, your vitamin D test results will be made available to you (see above)

## **Is the study confidential?**

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All data collected in this study will be maintained on confidential password protected databases at the Menzies Research Institute. Access will be limited to the researchers and support staff only.

### **Who do I contact if I have any questions?**

The contact person for questions relating to the study is Helen Steane on 6226 7700 or toll free 1800 638 124. You may also contact one of the Chief Investigators, Dr Tania Winzenberg or Professor Graeme Jones on 6226 7700 or toll free 1800 638 124.

### **Concerns or complaints?**

This project has received ethical approval from the Southern Tasmania Health & Medical Human Research Ethics Committee. If you have any concerns of an ethical nature or complaints about the manner in which the project is conducted, you may contact the Executive Officer of the Human Research Ethics Committee (Tasmania) Network on 03 62267479, who can direct participants to the relevant Chair that reviewed the research.



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