record

a study of fracture prevention

What is the study about?

- To find out if calcium and/or vitamin D tablets can help to prevent further broken bones.

What will you be asked to do if you agree to take part in the study?

- Fill in a questionnaire about your health at the start of the study.
- Take two tablets once each day until the study ends in about 2003.
- Fill in more questionnaires, at four monthly intervals.

What other details will be needed for the study?

- We will collect some additional information about contacts with the hospital and your GP.

What is the aim of the study?

You have been treated in this hospital for a recent broken bone. This study is trying to find a way to stop people aged 70 and over having any more broken bones. One way that is often suggested is to give tablets which will increase the amount of calcium getting to the bones. There are other treatments but they have not been formally evaluated in the elderly.

Everyone gets some calcium in their diet. Some people who drink a lot of milk and eat a lot of cheese may take in as much as they need, but some others do not. Even if there is enough calcium in your food, it may not get to the bones because, particularly during the winter, people may not have enough vitamin D in their bodies.

Two big research studies have been done to see whether giving vitamin D and calcium helps reduce the number of fractures older people get. Despite these studies, it is still not clear whether vitamin D or calcium on their own prevent broken bones, or whether it is necessary to take them both together. This study has been funded by the Medical Research Council (MRC) to find out which is the best treatment.

Is there anyone who should not take part in the study?

People with kidney or bladder stones should not take part in the study as treatment may make the problems worse.

If I agree to take part, how will I be asked to help?

If you agree to take part, you will be given instructions about how you yourself can help reduce the risk of breaking another bone. As well, you will be given tablets to take each day, which will be either calcium, or vitamin D, or a combination of calcium and vitamin D, or a non-active tablet that looks and tastes the same.

This study is what is called a 'randomised controlled double blind trial'. This means that you will not know yourself until the end of the study whether you are getting vitamin D or calcium, or both, or neither.

Until the end of the study, only a small group of researchers in the study centre in Aberdeen will know what you are receiving, so that they can send you the correct tablets. There is one chance in four that you will not be getting either vitamin D or calcium, but three chances in four that you will be getting at least one of them. This type of study is the best way of making sure that we really know by the end whether the treatments work or not. You may be invited to help in other studies related to this one.

Could there be unwanted side effects to the medication?

In the doses being given, the risk of unwanted effects from either calcium or vitamin D is very small. A few people in previous large studies have complained of indigestion, bowel upsets or loss of appetite. These problems are more likely to arise for other reasons. If you are ever worried please ask your GP. He/she will know you are taking part in the study and if necessary can find out what tablets you are getting.

The study will last until about 2003.

Is there anything else I should know about my part in the study?

If you do decide to join, the study nurse will collect some details to send to the study centre in Aberdeen. These details will allow us to keep in touch with you. We will also ask you to tell us the name and address of a relative or close friend who we could contact if we were unable to get in touch with you during the study.

You are under no obligation to take part in this study, and can withdraw from it at any time without it having an effect on your care in other ways.

We will notify your family doctor and keep in touch with him/her during the study. We will also collect some additional information from hospital and NHS records. All the information we collect will be confidential and will only be available to properly authorised members of the research group.

Soon after you join, you will receive by post your first supply of tablets, which should last for four months. The study nurse will contact you in about two weeks to check that the tablets have arrived and that you are not having any difficulties.

You should take two tablets once every day. A new supply will be sent to you every four months, along with a short questionnaire, asking some simple questions, including checking that you have not had another broken bone.

Further Information

If you need any further information, or have any concerns about the medicines or taking part in the study, please contact:

Researcher
Lynne Swan Tel: 01224 553140

If you are still unhappy with any aspect of the study please discuss these with Professor Kay-Tee Khaw, an independent expert not involved in running the study. She can be contacted through the Study Office.

RECORD Study Office
Health Services Research Unit
University of Aberdeen
Foresterhill
Aberdeen AB25 2ZD
Tel: 01224 554335 Fax: 01224 403018

Local Investigators
Prof. J Hutchison/Prof. G Page
Aberdeen Royal Infirmary
Aberdeen
Tel: 01224 553007/553307

This study is sponsored by the MRC and adheres to the standard MRC Guidelines for Good Clinical Practice in Randomised Controlled Trials. The MRC does not believe that you will suffer injury by participating in this trial. The MRC will, however, sympathetically consider claims for compensation in the absence of negligence. Your right at law to claim compensation for injury where you can prove negligence is not affected.