

Vitamin D levels in people with MS

Online and paper patient information sheet

You are being invited to participate in a research study. Before you decide whether to take part, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information and ask for anything that is unclear to be explained.

What is the purpose of this study?

This study is to look at vitamin D levels in people with MS across the UK, and factors that may affect these. As part of this study, we will be asking you to take a finger prick test to look at your vitamin D levels, and studying whether this is a good way of measuring vitamin D levels in future studies. We will also use these samples to look at things that may affect vitamin D levels in individuals.

We are asking that all people with MS who take part in this study do so with a friend who does not have MS, who lives within 50 miles of them. This friend should not be a relative, and should be of the same gender and approximately the same age as you. They will be asked to provide a finger prick blood sample, a cheek swab, and answer a few questions about their diet and any vitamin supplements they take. When we look at the results of this study, we will not pair you directly with your friend, but instead look at patterns across the UK in people with MS, and patterns across the UK in people without MS. It is important for this study that you are willing to ask a friend to take part, as we need to be able to compare people with MS to those without MS. We will not be asking people without MS as many questions as we are asking people with MS, for example we are not asking them for details of any other medical conditions. If none of your friends are willing to take part in the study, you will still be eligible to take part, however.

Why have I been asked to take part in this study?

You have been asked to take part in this study because you have a diagnosis of MS.

Do I have to take part in this study?

You do not have to take part in this study. If you do decide to take part, you can keep this sheet and will be asked to sign a consent form. If you do decide to take part, you can change your mind and withdraw from the study at any time. Your decision whether to take part or not will not affect any part of your medical treatment or the standard of care you receive.

What will happen to me if I take part in this study?

If you decide to take part in this study you will first be asked to complete a brief questionnaire about your age, where you live, and your MS. After this, you will be asked to answer some more detailed questions about your MS, your diet and any vitamin supplements you might take, and other things that can be associated with vitamin D levels. We ask that you enter this information via the MS Register, however, if this is not agreeable to you or not possible, then this can be done by post.

We will then send you a pack to take a finger prick blood test and a cheek swab. A friend or relative can help you to take these sample if you need. We will send a second pack to give to a friend, who will also need to complete a short questionnaire and take a finger prick blood test and cheek swab. Both packs will contain an envelope with prepaid postage and should be sent back when you have taken the samples.

The blood samples you and your friend provide will be tested for vitamin D levels, and the cheek swab samples will be tested for genes that can affect a persons levels of vitamin D. We will not be doing the genetic tests on everyone taking part in this study. We will only do these tests on people with the highest and lowest levels of vitamin D in their blood samples. This means that if your vitamin D test is average for people with MS we will not do any genetic tests on you. The genetic tests do not predict any diseases, but can influence someones vitamin D level, and we want to see if these are important in people with MS. We may do additional tests on the blood samples to examine factors that can influence a persons vitamin D level, or look at things that may be affected by vitamin D.

One of the questions that you are asking is how much vitamin D is in the supplements I take, how can I find out this information?

Most supplements contain vitamin D in the form of vitamin D3.

If you are taking supplements that only contain vitamin D (or vitamin D with added calcium), this would usually be on the front of the packet. It is usually a number followed by either IU or mcg. You can give us either number.

If you are taking multivitamins, then the amount of vitamin D will be in a table, which is usually on the back of the packet. The usual amount of vitamin D in a multivitamin is 400IU. If you can't find the amount of vitamin D written anywhere on your multivitamin then please just let us know the brand of multivitamin, and how many tablets you take.

If you are taking more than one supplement that contains vitamin D (e.g. multivitamin and extra vitamin D) then please tell us the amount of vitamin D in both of these.

If you have had vitamin D injections then please tell us that you have had these. You do not need to add a dose for these, as these are only available in high doses.

What are the possible disadvantages and risks of taking part in this study?

The main possible risk of taking part in this study is a slightly sore finger where the finger prick blood test has been taken. There are no risks associated with providing the cheek swab.

What are the possible benefits of taking part in this study?

We hope that the results from this study will help us to better understand vitamin D levels in people with MS across the UK, which will help us to design any future trials around vitamin D in MS in the UK.

Will this study influence the treatment I receive?

This study does will not influence any care or of the treatments that you may receive. It will not form any part of your medical record.

What will happen to information about me during this study?

The information gathered as part of this study will be stored separately from any information that could be used to identify you. The answers that you provide to questions will be stored online via the MS Register, which encrypts the information and stores it separately to any information that can be used to identify you. The MS Register has ethical approval to store information in this way.

Any blood or cheek swab samples left over at the end of this study may be used in future studies with appropriate ethical approvals, however, researchers in these studies would not have access to any information that could be used to identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Queen Mary University of London is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Queen Mary University of London will keep potentially identifiable information about you for 20 years after the study has finished.

Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Queen Mary University of London and the MS Register will use your name, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals Queen Mary University of London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The MS Register will pass these details to Queen Mary University of London along with the information collected from you. The only people in Queen Mary University of London who will have access to information that identifies you will be people who need to contact you to feed back your vitamin D level, or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

Queen Mary University of London will keep identifiable information about you from this study for 20 years.

You can find out more about how we use your information at <http://www.jrmo.org.uk/>

Who has reviewed this study?

This study has been reviewed by the London-Stanmore ethics committee, who have approved the ethics of this study.

Who is organising and conducting this study?

This study is being organised by Dr Ruth Dobson at the Wolfson Institute of Preventative Medicine, Queen Mary University London. It is funded by the MS Society of Great Britain. Further information about this study can be obtained by contacting Polly Rawlinson on telephone no 0207 882 5698 or email p.rawlinson@qmul.ac.uk.