INFORMED CONSENT AND HIPAA AUTHORIZATION TO PERMIT THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH PURPOSES

Control Group

Title of study: Vitamin D3 supplementation to prevent respiratory infection, including covid-19, in hospital workers: a pragmatic study

Principal Investigator (PI): Noud van Helmond MD

Phone Number: 716-880-9732

Sponsor(s): Cooper University Hospital

Funder(s): The Won Sook Chung Foundation

What does informed consent for a research study involve?

You are being invited to take part in a research study. This form is part of an informed consent process. It will give you information to help you decide if you want to volunteer for this research study. Volunteer means you choose to take part. You do not have to take part in this study to receive treatment at Cooper Hospital nor will your participation in this study affect any aspect of your employment with Cooper. If you decide to take part, you only need to complete the survey and click the 'submit' button. If you have questions at any time while taking the survey, you should feel free to call the study team member listed above and ask your questions until you receive answers that satisfy you.

What is the purpose of this research study?

Very few interventions have been proven to reduce the occurrence of respiratory infections other than either avoiding exposure to sick people and/or vaccination for specific diseases. However, recently there have been several research studies showing that supplemental vitamin D may be effective in reducing the chance of getting a respiratory infection and whether that infection becomes severe. Studies also have found vitamin D increases the activity of immune cells in the body as well as increasing compounds known as cytokines, which also control immune response to respiratory infections. Studies have also shown that low vitamin D is associated with getting more respiratory infections. Most vitamin D is made through a reaction that takes place in the skin when skin is exposed to the sun. People who live in the northern hemisphere, far away from the equator have greater risk of low vitamin D levels. States such as New Jersey and Pennsylvania would be states where residents would have higher rates of low vitamin D. In

addition, healthcare workers are a group of people at higher risk for getting respiratory infections because these workers come in contact with large numbers of people who are sick.

This study is being done to determine if healthcare workers taking a daily oral dose of vitamin D will get fewer respiratory infections than those who do not. A group of employees taking vitamin D for a 9-month period (the intervention group) will be compared to a group of employees who have not taken vitamin D as part of the study (the control group). You are part of the control group and will not receive vitamin D. It is necessary to determine how many people in the non-intervention group took vitamin D during the course of the study and at what dose.

Who may or may not take part in this study?

You are being asked to take part in this study because you are an employee working for the Cooper Health System. As part of the control group, you were randomly selected to take a survey. To take part in this study:

-You must be at least 18 years old

How long will the study take and how many people will take part?

Your participation in this study will be the time it takes for you to complete the survey. It is expected that 7,600 people will participate in the study. 4,708 will be in the intervention group, while 2,892 will be in the control group. The control group will be approached to take part in a survey.

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

All subjects in this study will be Cooper employees. You have been contacted via email by a member of the study team and asked if you would agree to participate in this part of the study. If you agree to participate in this part of the study, you are asked to complete a survey with questions about your medical history, your height and weight, and whether you have used vitamin D in the past nine months and at what dose. Completing the survey should take approximately 5 minutes.

Completing the survey is solely for research purposes.

To measure the effect of vitamin D supplementation the study team will receive anonymized aggregated numbers of infections for the participants in the study from Cooper Employee Health. Additionally, anonymized aggregated health care utilization and health care cost data will be provided to the study team through insurance data. The study investigators will at no point have knowledge of individual data but will only receive total group numbers.

What are the possible risks or discomforts if you take part in this study?

The only risk from participating in this survey is the risk of your information unintentionally being disclosed outside the study. This risk is low. We will follow standard best practices to protect your information and only study team members will have access to the data collected in the study.

What if you are pregnant or become pregnant?

You may not participate in this study if you are pregnant.

Are there any benefits if you take part in this study?

There are no benefits to you if you take part in this part of the study.

What are your alternatives (other choices) if you do not take part in this study?

You may choose not to take part in this study. The alternative is to not take part in this study.

How will information about you be kept private?

Information about you related to this study will be kept as private as possible. A study number will be used instead of your name on the survey. The study team may need to let other people look at the data you provide on the surveys. If that is the case, they will only be able to view your data that are identified by your study number, not your name. Only the study team will be able to link your study number to your name, date of birth or email address (see the HIPAA authorization below for the list of people who may need to inspect your study records and the reasons they need to look at them). The list linking your identifying information with your study number and study files will be kept on a secured server that is only accessible to the study team members. If the results of this study are made public (e.g. at a scientific meeting or in a publication), the study team members will not use your name or any other identifying information.

Will there be any costs to you to take part in this study?

There are no costs to you if you take part in this study.

Will you be paid to take part in this study?

You will not receive any money for taking part in this study.

What will happen if you become sick or hurt because you are in this study?

There are no risks of being injured or hurt as a result of this study. That does not mean that you are giving up any of your legal rights.

If you believe that you have been injured or become ill because you took part in this study, you should call the Chief Medical Officer or his representative at (856-342-3071).

Who is funding this research and where is it being done?

The Won Sook Chung Foundation is funding the work on this study by the principal investigator and a research coordinator at Cooper University Hospital. The Chung Foundation supports research on natural supplements and other aspects of integrative medicine. Co-investigator Dr.

Myung K. Chung is the president of the Chung Foundation. Co-investigators Patrick J. LaRiccia MD, Tracy L. Brobyn MD, Kevin Q. Ng MD, and Brigid Bandomer RN are employees of the Chung Institute of Integrative Medicine.

Whom should you contact if you have questions?

You should call the Chief Medical Officer or his representative at 856-342-3071

(a) if you have any questions about your rights as a research subject;
(b) if you believe that you have not been told about all the risks, benefits, and alternative treatments;
(c) if you believe that you are being forced to stay in this study when you do not want to; or
(d) you have any complaints about the research.

If you have any questions about the research, you may contact the investigator listed on the front of this consent form. The principal investigator listed is responsible for the conduct of the research at Cooper Hospital. He is affiliated with the Cooper Health System. The investigator's address is One Cooper Plaza, 2nd Floor Dorrance Bldg Suite# D206, Camden, NJ, 08103. The investigator can be reached at the phone number given on the first page of this form.

If you have any questions about the research or your rights as a subject or any complaints about the research, you may also contact the Institutional Review Board (IRB) of the Cooper Health System. The IRB is responsible for protection of subjects participating in this research project. The address of the IRB is E&R Building, 401 Haddon Ave., Room 288, Camden, NJ 08103. The phone number is 856-757-7832.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site may include a summary of the results. You can search this web site at any time.

What will happen if you do not wish to take part or decide not to stay in this study?

You do not have to be part of this study. If you decide to be in the study, you may quit at any time. If you decide not to participate or to drop out of the study, your decision will not affect your care at Cooper Hospital nor will it affect your employment at Cooper either now or in the future. Either way, the doctors and institution at Cooper Health System will treat you the same way.

USE AND DISCLOSURE
OF PROTECTED HEALTH INFORMATION (PHI)
FOR RESEARCH PURPOSES

Will your information be kept confidential?

The privacy regulations of a law passed by Congress became effective on April 14, 2003. The law is called the Health Insurance Portability and Accountability Act, HIPAA for short. The law gives subjects in research studies certain rights about their protected health information. Protected health information (PHI) is information about a person's physical or mental health that can be identified with or linked to that particular person. If you sign this form you are giving the investigators, their staff, and certain other people described in this form your permission to use your protected health information for this research study.

The information collected about you for this study is called "protected health information" (PHI). It includes your name, date of birth, email and the medical history you report to us. Your medical records within the Cooper University Health Care system will not be accessed by the study team at any time. All of this information is being collected because you are participating in this research study.

To help maintain the confidentiality of your study records, only the study team will have access to the data you provide during the study. This data, including your name, date of birth, email address and the medical history you report to us, is stored in a secure data collection program that is password-protected. You will be assigned a subject number. All of your study related-information collected will have only your subject number. Identifying information, like your name, will kept in the secure data collection program. Your study documents will be stored in a locked file cabinet at the end of the study. The information from this study may be published in scientific journals or presented at scientific meetings but you will not be personally identified in these publications and presentations.

By signing this form, you are allowing the following people or groups to have access to the information described above (your PHI).

The research team, which includes the investigator listed on this form and other personnel involved in this specific study who need to analyze the data.

Cooper's Institutional Review Board (IRB), a committee that reviews, approves, and monitors research involving human subjects may look at your study records.

All of these people and entities are obligated to protect your PHI.

You have the right to limit the use and sharing of your PHI, and you have the right to see your research study records and know who else is seeing them. You will not be allowed to see your health information that is created or collected during the course of the research. After the research is finished, however, you may see this information.

By completing the survey, you are authorizing us to use and disclose your PHI until the end of the research study. You may revoke this authorization to use and share your PHI at any time by contacting the principal investigator, in writing, at the address on the front of this form. If you decide not to authorize the investigator to use and disclose your PHI or you revoke this authorization, you will no longer be able to participate in this research study; however, the PHI that has already been collected may still be used.

VOLUNTARY PARTICIPATION

I have read the above informed consent. I voluntarily consent to take part in this study. I also agree to the use and disclosure of my protected health information for this study (name, date of birth, email address and the medical history I report to you). I understand by agreeing to consent, I am not giving up any of my legal rights. I will have the opportunity to download a copy of this consent form for my records.

Do you consent to take part in the study? YES/NO