THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

DAILY: Vitamin D, Aspirin, Exercise, Low Saturated Fat Foods StudY in Colorectal Cancer Patients with Minimal Residual Disease

2021-0320

Study Chair: Alisha Bent, MD

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this clinical research study is to learn if lifestyle changes (such as diet and exercise) combined with daily aspirin and vitamin D can affect the likelihood of advanced colorectal cancer coming back (recurring).

This is an investigational study. Aspirin and vitamin D are FDA-approved and commercially available. However, it is considered investigational to use aspirin and vitamin D as treatments to prevent the return of cancer. The study doctor can explain how aspirin and vitamin D are designed to work in this study.

Lifestyle changes combined with aspirin and vitamin D may or may not help to lower the risk of colorectal cancer returning. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment.

You can read a full list of potential side effects below in the Possible Risks section of this consent.

You may take aspirin and vitamin D in this study for up to 90 days.

You and/or your insurance provider will be responsible for the costs of the aspirin and vitamin D while taking part in this study.

You may choose not to take part in this study. Instead of taking part in the study, you may choose to receive standard of care monitoring (such as routine blood tests and imaging scans). The study doctor will discuss the possible risks and benefits of this monitoring. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help the doctor decide if you are eligible:

- Blood (about 1½ tablespoons) will be drawn for routine tests, circulating tumor DNA (ctDNA) testing, and research testing. ctDNA testing is a measure of how much tumor DNA (genetic material) is in the blood. Research testing in this study will be done to understand more about markers of inflammation in the blood, as well as hormone testing.
- If you can become pregnant, a urine sample will be collected for pregnancy testing. To take part in this study, you must not be pregnant.
- You will have an MRI and/or CT scan to check the status of the disease.
- You will complete a questionnaire about your diet (such as how often you eat and the types of food you eat). It should take about 15 minutes to complete this questionnaire.
- Before Day 1 of the study, you will meet with a licensed dietician to discuss your diet and to make suggestions on possible diet changes. This meeting should take about 15-20 minutes. If needed, this meeting can happen virtually (either by phone or by video conferencing methods, such as Zoom).
- You will be given a Fitbit to wear during the study. You will need to download the Fitbit application ("app") to your personal cell phone, which will allow the data from the Fitbit to be collected and shared with the study team. Instructions will be included with the Fitbit, but you may ask the study team for help to set up the app and/or Fitbit, if needed.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Up to 19 participants will be enrolled in this study. All will take part at MD Anderson

Study Drug Administration and Study Tests/Procedures

If you are found to be eligible to take part in this study, you will take aspirin and vitamin D by mouth every day for up to 90 days. The study staff will tell you how many tablets/capsules to take each day. You will be given a study drug diary to write down when you take dose of aspirin and vitamin D.

You will also continue to wear your **Fitbit every day for up to 90 days**. You should try to exercise (such as walking, bike riding, or using the elliptical machine) for at least 2½ hours every week, but you should do what is comfortable and safe for you.

Two (2) times every month for 3 months, you will be called by a dietician for a coaching session. During each session, you will be asked about your diet and exercise/lifestyle changes. You will also be reminded to complete your monthly questionnaire (see below). Each session should last about 15-20 minutes.

At the **end of each month for up to 3 months,** you will complete the questionnaire about your diet. A link to the questionnaire will be emailed to you. If you do not complete the questionnaires, you may be asked to answer them during your coaching session.

End-of-Study Visit

At about Day 90:

- Blood (about 1½ tablespoons) will be drawn for routine tests, ctDNA testing, and research testing.
- You will have an MRI and/or CT scan to check the status of the disease.
- You will complete the diet questionnaire.

Your participation in this study will be over after the 90-day visit (unless you agree to participate in the optional follow-up, described below under “Optional Procedures for the Study”).

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Side effects will vary from person to person, and some may occur after you have stopped receiving treatment. Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures.

Aspirin Side Effects

Common (occurring in more than 20% of patients)

- stomach and/or small intestine ulcer

It is not well known how often the following side effects of aspirin may occur.

- changes in heart rhythm
- fast heartbeat
- swelling
- low blood pressure (possible dizziness/fainting)
- agitation
- swelling of the brain (possible headache and/or mental status changes)
- coma
- confusion
- dizziness
- fatigue
- headache
- fever
- difficulty sleeping
- nervousness
- tissue swelling
- skin rash
- hives
- abnormal blood acid/base balance (possible organ damage)
- dehydration
- high blood sugar (possible diabetes)
- low blood sugar (children)
- high blood levels of potassium (possible kidney failure)
- high blood levels of sodium (possible weakness and/or swelling)
- small intestinal ulcer
- upset stomach
- abdominal pain
- digestive system ulcers
- irritation of the lining of the stomach
- heartburn
- nausea
- stomach pain
- vomiting
- increased risk of bleeding
- low platelets, red blood cells
- DIC (breakdown of the blood clotting system) (possible severe bleeding, organ dysfunction, and/or organ failure)
- low birth weight
- pregnancy and labor may take longer
- stillbirth
- liver damage (possibly due to inflammation)
- bone destruction (hip bone)
- breakdown of muscle tissue (possible kidney failure)
- weakness
- hearing loss
- ringing in the ears
- kidney inflammation (possible kidney damage/failure)
- death of kidney tissue (possible kidney failure)
- kidney failure
- decreased kidney function
- difficulty breathing (possibly due to narrowing of the airways)
- fast breathing
- swelling of the vocal cords
- fluid in the lung (possible difficulty breathing)
- life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)
- Reye's syndrome (disorder that causes brain and liver damage)

If taken as a suppository, aspirin may cause narrowing and/or irritation of the rectum.

Vitamin D may cause nausea, vomiting, loss of appetite, constipation, diarrhea, weight loss, a metallic taste, increased thirst, dry mouth, increased urination, cloudiness in the urine, muscle pain, and/or bone pain. It may cause headache, weakness, drowsiness, unusual tiredness, loss of sex drive, irregular heartbeat, calcium deposits (hard lumps) in tissues other than the bone, and/or itching of skin. It may cause mood changes, runny nose, eye irritation, and/or increased sensitivity of the eyes to light. It may cause redness and/or discharge of the eye, eyelid, and/or lining of the eyelid.

Using the drugs together may cause side effects that are not seen when each is given alone. The study drug combination may also increase the frequency and/or severity of the side effects listed above.

Other Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. When a CT scan of the abdominal area is taken, material may be inserted into the rectum to better define the bowel. You will usually drink liquid to help define various abdominal organs. This may cause nausea and/or vomiting. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets, and data will continue to be stored securely after the study. Only authorized research staff will have access to study data. Plans for continued storage of study data will be consistent with protocol and clinical research contract requirements, applicable regulations, and the MD Anderson Medical Records Policy (#CLN0554).

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant will result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

You do not have to agree to the optional procedures in order to take part in this study. There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure #1: If you agree, blood (about 1½ tablespoons) will be drawn on Day 45 for research testing.

Optional Procedure #2: If you agree, you will continue having MRI and/or CT scans to check the status of the disease about every 3 months for as long as the study is open and you are enrolled. If the disease gets worse, you will stop having these scans.

Optional Procedure Risks

The risks for optional **blood draws and MRI/CT scans** are the same as the risks described above.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to have blood drawn on Day 45 for research testing?

YES **NO**

Optional Procedure #2: Do you agree to continue having MRI/CT scans to check the status of the disease?

YES **NO**

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result

from your participation in this research.

You will receive no compensation for taking part in this study. However, you will be able to keep the Fitbit if you complete the study through the 90-day follow-up visit.

Additional Information

4. You may ask the study chair (Dr. Alisha Bent, at (713) 798-2828) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research.

Use of data and samples for future research is required. If you do not want your samples and/or research data to be used, you should not enroll in this study. If you withdraw your authorization, your samples will not be included in any further research studies.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research
Samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will do its best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by federal law.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected. If you withdraw from the study, the study staff may ask if they can continue collecting the results of routine care from your medical record.

E. 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 will include a summary of the results. You can search this Web site at any time.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT