Plant Pigments for Human Health: Impact of Lycopene and Anthocyanins on Bioefficacy of Provitamin A Carotenoids From Carrots

NCT05319548

8/19/2022

University of Wisconsin-Madison
Consent to Participate in Research

Study Title for Participants: Carotenoid and Anthocyanin Bioavailability and Antidiabetic Activity from Multicolored Carrots

Formal Study Title: Plant Pigments for Human Health: Determining the interactions of anthocyanins and carotenoids from multicolored carrots by assessing the impact of co-ingestion on the bioavailability of provitamin A carotenoids and the impact on each pigment groups' respective antidiabetic activity.

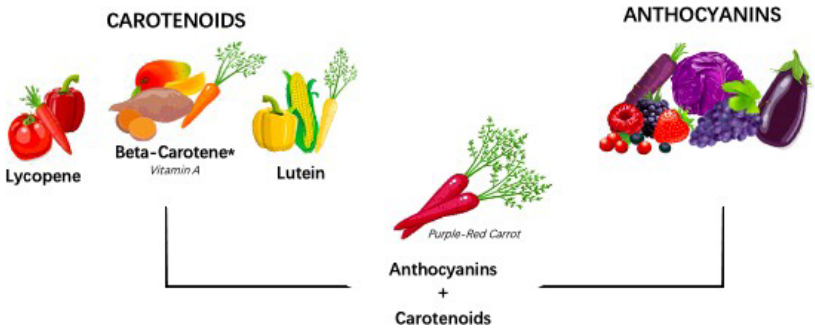
Lead Researcher: Kayla Kaeppler, Ph.D. Candidate (608-516-9949)

Principal Investigator: Sherry Tanumihardjo, 1415 Linden Dr. Madison, WI 53706

Institution: University of Wisconsin-Madison Dept. of Nutritional Sciences

Key Information

Two substances that are responsible for a majority of the colors that you see in fruits and vegetables are carotenoids and anthocyanins. **Carotenoids** are the substances that give the red, orange, and yellow colors to plants. For example, carrots are orange because of -carotene, tomatoes are red because of lycopene, and corn is yellow because of lutein. Some of these carotenoids turn into vitamin A when they are eaten. The other pigment group, **anthocyanins**, are substances that give the blue, purple, and red colors to plants. Fruits and vegetables with anthocyanins include berries, grapes, eggplant, and more. Some vegetables, specifically the purple-red carrot, contain *both* carotenoids and anthocyanins. Studies have shown that carotenoids and anthocyanins are linked to a decreased risk of certain diseases, such as diabetes and cancer. Individually, these substances are linked to beneficial health effects, and with that in mind, there have been efforts to create/grow foods that include multiple carotenoids and anthocyanins with the hope of increasing those benefits.



Why are researchers doing this study?

Our laboratory is trying to measure the amount of carotenoids and anthocyanins that you absorb from your food, and if eating the substances at the same time changes that absorption. We are also looking at the effect that these substances have on your blood glucose levels.

We are looking for 12 individuals to participate in this study. You are invited to take part in this study comparing the amount of carotenoids and anthocyanins absorbed from different types of carrots. The benefit to society from these studies will be the promotion of different forms of naturally grown carrots. It will also help decipher if there is a beneficial or detrimental effect of eating foods with both carotenoids and anthocyanins at the same time. This will give people more choices to increase their vegetable consumption.

What will I need to do in this study?

This study has three parts to it. You will be required to visit the Clinical Research Unit for each day that blood draws are taken. The Clinical Research Unit is located in the UW Hospital (600 Highland Ave. Madison, WI 53792). Blood draws will be taken just prior to treatment (drinking carrot juice) and at 15m, 30m, 45m, 1h, 2.5h, 4h, 6h, 9h, 24h, and 72h after consuming carrot juice. You will have 11 blood draws taken within 3 days. These will be 12 mL blood samples (about 2 teaspoons), similar to what might be done at a doctor's office visit. This amounts to ½ cup during each part of the study. The total time you will be involved in the study will be 53 days.

We will also ask you to avoid some foods during the study and 7 days before the study begins. Also, you will be required to avoid alcohol for a short time before and during the experiment. You will be given a list of foods that you should avoid during this study. You will also be required to keep track of what foods you have eaten during this time period. You will be given clear directions of when and when not to eat and drink certain foods and beverages during the full course of the study.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are some reasons I might – or might not – want to be in this study?

Benefits:

You will be educated on the benefits of incorporating good nutrition; such as increasing the amounts of fruits and vegetables you eat, into your everyday foods. We will also inform you of your individual profile of the carotenoids, vitamin A, and anthocyanins in your blood. This will help you to see how you compare to the published normal values.

You will be compensated in the form of $300 upon *completion* of the entire study. This will be paid by check and will be received about three weeks after the study. If you do not remain in the study until the end, you will be paid $100 for each part of the study you complete.

Risks:

All ingredients of foods provided for you are attached. If you have an allergy to **ANY** of these ingredients, then **DO NOT PARTICIPATE IN THIS STUDY**. Blood draws will be performed by a trained medical technician to minimize any pain or bruising that could possibly occur. The level of risks are minimal but risks do include bruising around the area where the needle enters the vein, infection if not properly cleansed, bleeding if you do not apply appropriate pressure, small blood clot formation, swelling of the vein, stinging at the site of needle entry and rarely, dizziness or fainting.

Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?

When you go to a health provider for care, the provider focuses on how to help you as an individual. When you take part in a study, you are helping to answer a research question, like how safe or effective a treatment is, or what dose to use. Treatment is based on a study plan, not on you as an individual.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the lead researcher, Kayla, at (608)-516-9949.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

If I take part in the study, what will I do?

If you decide to participate, the research team will ask you to consume a "low carotenoid diet" for one week prior to the beginning of each of the three treatment periods, and a "low anthocyanin + low carotenoid diet" three days prior to and during the treatment period . Lists of foods that you must avoid/are allowed during each diet will be provided along with a "sample menu" of what you might eat at some meals. A study calendar will be provided, which will show you what days you need to come in to the Nutritional Sciences Department for blood draws and meals. The calendar also states what days alcohol may be consumed and what days it absolutely cannot be consumed. If you agree to participate in the study, we will take your weight, height, and age.

In this study, there are three arms (test periods) that consist of 7 pre-treatment days and 4 day treatment periods, followed by a 10 day rest in which you will be able to consume your normal diet. The three treatment periods of the study differ by the *color of carrot used for the juice*.

The three groups are:

1) Purple carrot;

2) Purple carrot with red core;

3) Red carrot;

The treatment (type of juice) you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will, however, have drank all three of the juices by the end of the study. You will not be told which treatment you are getting.

One week prior to Part 1:

For 7 days, follow the "Low Carotenoid Diet."

Three days prior to Part 1:

You will be instructed to follow the "Low Anthocyanin + Low Carotenoid Diet".

For Part 1:

Continue on "Low Anthocyanin + Low Carotenoid Diet."
Beginning on the first day of each treatment period (Treatment day) of the study subjects will report to the Clinical Research Unit on campus between 7 am and 8 am (depending on designated start time), **fasted** (do not eat for ***10 hours before*** this visit, however, water can and should be consumed). You will be given a time for your blood draws. After baseline draws are made, required breakfast will be given to all subjects consisting of carrot juice, white bread, and water.

A IV catheter will be inserted into your arm for the first 9 blood draws to avoid multiple individual blood draws.
Blood draws will be at 15m, 30m, 45m, 1h, 2.5h, 4h, 6h, 9h, 24h, and 72h after consuming the carrot juice. Blood samples will be collected by a trained medical technician. The blood samples are routine samples, like during a physical exam, taken from the arm vein.
After the 72h blood draw is taken, you resume your typical diet for the next 10 days.
Moderate amounts of alcohol are allowed, but not required, during the rest period as written on the provided calendar.

After the week of regular diet has passed, you will begin Part 2. The times that you have to come in for blood draws and meals are the **same as in part 1**, however, now you are consuming juice from a different carrot type for breakfast.

After the 10 days of regular diet has passed, you will begin Part 3. The times that you have to come in for blood draws and meals are the **same as in parts 1 and 2**, however, now you are eating a different carrot type for breakfast.

What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

What happens to the information collected for the research?

We have strict rules to protect your personal information**.** We will limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information.

All information collected will be confidential between you and the researchers conducting this study. All blood samples and information collected will only be seen by the researchers of this study. During analysis, the results will be coded. The codes will only be linked to your name in a locked file kept in a designated computer in the UW-Department of Surgery or in Dr. Tanumihardjo's lab. You will not be identified in any publications resulting from this study. All blood samples will coded and will be stored in a locked lab and will only be used for this study. Specimens will not be stored for any other use once the study is complete.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program. We may also have to tell appropriate authorities,

such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Also, with appropriate confidentiality protections, we might use information and biospecimens that we collect during this study for other research, or share it with other researchers without additional consent from you.

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.

Will information from this study go in my medical record?
It is not guaranteed that no information from this study will end up in your medical record.

Can I be removed from the research without my agreement?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- your health changes and the study is no longer in your best interest
- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or researchers

What else do I need to know?

What happens if I am injured or get sick because of this study?
If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

If it is an emergency, call 911 right away or go to the emergency room.
For non-emergency medical problems, contact the study team for instructions and contact your regular health care provider.
Call the Lead Researcher, Kayla Kaeppler at 608-516-9949 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
Your health insurance company may or may not pay for this care.

No other compensation (such as lost wages or damages) is usually available. UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

Will I receive anything for participating?
You will be compensated in the form of $300 upon *completion* of the entire study. This will be paid by check and will be received about three weeks after the study. If you do not remain in the study until the end, you will be paid $100 for each part of the study you complete.

Permission to communicate about the study by email
We are requesting your email address as a way to keep in contact and communicate with you. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the Lead Researcher, Kayla Kaeppler, at (608)-516-9949. You do not have to provide your email address to participate in this study.

How many people will be in this study?
We expect about 12 people will be in this research study.

Who is funding this study?
This research is being funded by [Insert name of sponsor].

Please take as much time as you like to think this over, but a response is required by _____[Will update with correct date once have IRB approval and anticipated schedule is adjusted]. Before you sign this form, ask any questions you have regarding this study. We will fully answer all your questions before, during, and after your participation in this study.

Agreement to participate in the research study

If you sign the line below, it means that:

- You have read this consent form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
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Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	