Fisetin Study

Title: Clinical translation of senolytic therapy with fisetin to improve vascular function in older adults

Principal Investigator: Matthew Rossman, PhD
Location: Main CU Boulder Campus

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Goals of this Clinical Trial:

- Determine if taking fisetin, a natural compound found in strawberries, improves blood vessel function in older adults
- Determine if taking fisetin improves brain function in older adults

Integrative Physiology of Aging Laboratory

University of Colorado Boulder

Why is this research important?

As we age, our body and brain functions decline. This is in part due to too many "senescent" cells being in our body. Senescent cells are aging cells that do not work as well as non-senescent cells. Their presence can lead to declines in heart and brain function. This study may help society by providing information about a natural compound, fisetin, found in strawberries and onions, for targeting these aging cells to hopefully improve heart and brain function.

Who is eligible to participate?

We are looking for individuals:

- **65 years or older**
- **Willing to consume fisetin or placebo capsules for 6 days**

We will further assess your eligibility once you complete this form.

What do I receive for participating?

- **Payment for your time (up to $240 USD)**
- **Results from the tests we perform: bloodwork, blood pressure, artery stiffness, brain function, heart health, etc.**

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What happens at the screening visit?

Once we review your screening form, you will be invited to partake in a screening visit where we will explain the study to you and perform some tests to see if you qualify for the study. This can either be done completely in-person or on two separate days, one over Zoom and one in-person. The entire visit takes ~2 hours and requires you to be fasted (no food or drink other than water) for 5 hours prior. *If you opt for the two-part screening, you do not need to fast before the Zoom part.*

The screening visit entails:

- Informed consent (review of the study and the risks/benefits)
- Paperwork and questionnaires about your medical and activity history
- Height and weight measurement
- Blood collection (blood sugar, cholesterol, etc.)
- Resting electrocardiogram (ECG) - measures heart electrical activity
- Blood pressure and heart rate measurement

What happens during the study?

This study requires ~13 hours of your time (8 visits) over the course of ~6 weeks.
If you take part in a follow-up visit, it requires ~14 hours of your time (9 visits), ~11 weeks.

If you qualify for the study, you will be invited to take part in baseline testing which entails:

- Blood vessel function and artery stiffness measures (performed with a sensor placed on the surface of your skin)
- Brain function measures: measured by tests on an iPad and on paper and by using a sensor on your skin to measure blood flow to your brain
- Blood draw to assess inflammation and cell aging
- Questionnaires about your activity, sleep, etc.

→ You'll then be randomly assigned to one of two groups: fisetin or placebo (a capsule that looks like fisetin but does not have fisetin in it). You will take the supplement for 6 days over the course of 2 weeks.

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~1 week after finishing your final capsule: You will complete post-testing, where we will repeat the same measures performed at baseline so we can see if the supplement had an effect.

← ~1 month after post-testing: You can complete optional follow-up testing where we will perform similar measures to some of the ones performed during post-testing. This way, we can see if any changes that were seen from baseline to post-testing were sustained, even without taking the supplement.

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FAQs

Q: Where are you located?
A: Our facility is located on the main CU Boulder Campus in the Ramaley West Extension. We are directly south of the Student Rec Center. You can click here for an exact location.

Q: Where can I park?
A: We offer parking close to our facility in Lot 380. Parking is free for the duration of your visits to our facility. If you require assistance getting from your car to our facility, we have golf carts we can use to help transport you.

Q: I have some vacations coming up. Can I still be in the study?
A: We are flexible and can accommodate most vacation schedules. For this study, we have some more rigid time requirements, but we can work around vacations up to two weeks. Please communicate any upcoming vacations to us early on.

Q: How long are you taking participants for?
A: We are enrolling participants on an ongoing basis. If you have an extended trip (>2 weeks) coming up, we can schedule you to undergo screening after your trip.

Q: What are the ingredients in the fisetin and placebo supplements?
A: Each vegetarian capsule of the fisetin contains 8 mg of fisetin (from wax tree extract) and 15 mg of fenugreek seed galactomannans. The fisetin and placebo capsules also contain microcrystalline cellulose, vegetable cellulose (encasement of the capsule), silica, vegetable stearate, soluble fiber, sunflower lecithin.
Note: If you are allergic to any of these ingredients, you should not participate in this study. Please visit our website for information on other studies.

Q: How much of the fisetin or placebo will I take?
A: You will be given fisetin at a dose of 2 mg per kg of body weight. Each fisetin capsule contains 8 mg of fisetin. This means that for someone who weighs 70kg (~155 lbs), you would be taking 18 capsules each of the 6 days in order to ingest 140 mg fisetin per day. While we recognize this may seem like a lot of capsules, the capsules are low in fisetin content and the dosage we are using (2 mg/kg/day) is similar or lower than what has been utilized safely in other studies. For reference, some common medications, like metoprolol to control blood pressure, come in pills with 50 mg of the active ingredient. Hydroxychloroquine, used to control symptoms of autoimmune conditions, can have 200 mg of the active ingredient. The fisetin capsules only have 8mg of fisetin, thus we need participants to consume enough capsules to get the proper dosage.

Q: Should I stop taking my medications or change my diet/exercise routine for this study?
A: Unless instructed by your provider, you should continue taking all medications as prescribed. We may ask you to refrain from consuming over-the-counter supplements before your visits, but this is only for non-prescribed supplements. ***We ask that you inform us of any lifestyle changes during the course of the study, including changes in medications/supplements (doses included!), exercise routine, and diet, as these could potentially impact our measurements.***

Q: How is payment received?
A: You will be paid at the end of the study in the form of a check mailed to you ~1 month after you complete it. If you would prefer, we are happy to pay you throughout the study.

Q: I'm uncomfortable with having an individual of the opposite sex perform certain measurements on me (i.e., ECG which requires someone to touch my chest). Can you still accommodate me?
A: Your comfort and safety is our first priority. We can make adjustments in our staffing to ensure you feel comfortable. The same thing goes for any measurement--if you are uncomfortable with us performing any measurement, we can adjust to ensure your comfortability. Before each visit, we will send you in-depth details of the measurements and verbally obtain your consent to perform each measurement. You can opt out at any point in time.