

**UW**<sup>®</sup>

and

**FRED HUTCHINSON**  
**CANCER RESEARCH CENTER**  
A LIFE OF SCIENCE

THE  
BROCCOLI SPROUT  
STUDY



This study is a collaboration between scientists at the University of Washington and the Fred Hutchinson Cancer Research Center who have been working on understanding how vegetables are digested and transformed and what role they might play in helping the body prevent diseases. An earlier feeding study seems to indicate that different vegetable groups help the body in different ways, by different biological pathways. In the case of broccoli, it seems to increase the production of enzymes that help detoxify the body of potentially harmful substances that we are exposed to everyday.

From studies in our laboratory (on cells) we have been able to see that the active component in broccoli can help avoid interactions between drugs. Many patients fighting cancer for example, experience drug-drug interactions. This is why we will be giving you two medicines during the study, Midazolam and Rifampin. These do not cause any harm when taken together. We will, however, be able to see if the presence of the broccoli aids in maintaining each drug working separately. And, it is important to understand the level of effect of a little broccoli, one day, compared to a more routine exposure, like eating it everyday for a week. This study will answer important questions that can only be researched doing this kind of study!

**The need for three study periods:**

Each person is a little bit different because of genetic make-up. Also, each person eats different things in their normal diet that may affect the enzymes we are studying. Therefore, we will compare the results within each person during three combinations:

	Combination A	Combination B	Combination C placebo
Broccoli Sprouts	Yes	Yes	
Midazolam	Yes	Yes	Yes
Rifampin	Yes	No	Yes

**Order of the study periods:**

Each person will go through all three periods, all three combinations. The order will be random - like the toss of coin.

**Midazolam:**

Midazolam have been thoroughly tested for safety and is widely used especially in hospitals before surgery since it is a sedative and muscle relaxant. You will take a very small dose of 1 milligram (6-8 milligrams are given before surgery). Therefore, we do not expect side effects; you may experience mild sedation or temporary memory changes in the first hour or two. We will have an antidote for midazolam should you have an unusual response. Midazolam is relatively short acting. We will have nurses monitoring you during the entire time you are at our center. It is very important that you tell us if you have ever had any unusual or allergic reaction to midazolam or similar medications (see a complete list in the consent form under "What Are The Risks of the Study?").

**Rifampin:**

Rifampicin or rifampin is a used in conjunction with other drugs to eliminates the bacteria that causes tuberculosis (TB). You will take a dose of 300 mg. People being treated for TB usually get daily doses of 600 – 900 mg a day, for at least 3 months. You will be getting a smaller dose for 6 consecutive days during each study period. Your urine, stools, saliva, sputum, sweat, and tears may turn red-orange; this effect is harmless, though it may permanently stain soft contact lenses (if you use them).

## The daily activities for each period

All study activities will take place at the General Clinical Research Center, known as GCRC for short, it is located on the 7th floor of the South Tower, in the UW Medical Center.

**On days 1 and 8 of each period** you stay between 6-7 hours, starting at noon, take 1mg. of Midazolam and timed blood draws and urine collections.

**On days 2 thru 7 of each period** you stay for 1 hour, between 6 and 7 pm. to eat the soup and take the study capsule (during 2 periods, no pill during one period.) For the weekends we will provide the soup and the capsule for you to take home.

	DAY	DAYS	DAY
	1	2   3   4   5   6   7	8
	7 hours	1 hour each day	6 hours
	eat breakfast before 8:00 am		eat breakfast before 8:00 am
8:00 am	NO FOOD Drink water		NO FOOD Drink water
Noon	Take Midazolam  Lunch		Take Midazolam  Lunch
4:00	Timed blood & urine	No food after 4 pm	Timed blood & urine
6:00	Eat soup & take study capsule	Eat soup & take study capsule	
7:00	Home: collect urine overnight		

## The study consist of 3 periods

All three study periods have this same daily schedule:

Period	Day 1	2   3   4   5   6   7	8
1	7 hours	1 hour each day	6 hours

At least 2 weeks later:

Period	Day 1	2   3   4   5   6   7	8
2	7 hours	1 hour each day	6 hours

At least 2 weeks later:

Period	Day 1	2   3   4   5   6   7	8
3	7 hours	1 hour each day	6 hours

We will work on a schedule that works best for you, for example:

Noon-7pm	6 - 7 pm each day	Noon-6 pm
Thursday	F S S M T W at home -	Thursday
Or: Friday	S S M T W Th at home	Friday

In summary:

Number of weeks in study:							
1	2	3	4	5	6	7	8
	Period 1	2 weeks off		Period 2	2 weeks off		Period 3
Do not eat any cruciferous veggies: no broccoli, broccoli sprouts, cabbage, cauliflower, brussels sprouts, bok choy or kale. Do not eat any grapefruit or drink grapefruit juice.							

### **Things to consider:**

All study activities will take place at the General Clinical Research Center, known as GCRC, located in the UW Medical Center. This study requires you to stay at the center for 7 hours on a total of 6 days. We will work with you to find the dates that would be most convenient based on your schedule. On these days, when we will be giving you midazolam, we ask you that you not drive after you leave the center. Though we are giving you a very small dose and have not seen any participants feel a sedative effect, we ask you to take this precaution just in case your body has not processed all the midazolam by then.

### **Avoiding certain foods during the entire study:**

We ask that you do not eat cruciferous veggies starting one week before you start the first period of the study.. This means no broccoli, broccoli sprouts, cabbage, cauliflower, brussels sprouts, bok choy or kale for at least two months. Additionally, grapefruit also has an effect on the enzymes we are studying.

We ask you not to eat grapefruit or drink grapefruit juice for the entire study, a total of least two months.

We want you to limit caffeinated drinks to once in the morning before 9 am on the days 1 and 8 during the three study periods.

### **Blood draws and urine collections:**

For this study we will be collecting blood at specific intervals, every half-an-hour for two hours and then every hour thereafter until hour 6, on days 1 and 8 of each period. We will insert a small tube called a catheter into a vein on your forearm, that will stay in place for the 6 hours. This will make the draws much easier and less bothersome for you. Our experience is that participants feel quite comfortable, they have worked on laptops, handwritten papers and done other tasks with no inconvenience. The catheter does not hurt, if you feel any discomfort our study nurses will readjust it and the it should subside.

You will collect urine during 24 hours at the beginning and end of each study period. You will need to drop-off the collections at the end of the 24-hour period at the GCRC. We will work with you to develop a schedule that is most convenient for you.

### **The cheese soup you will eat every evening during each period:**

We will serve you creamy cheese soups, with or without broccoli sprouts. We use broccoli sprouts because the young sprouts contain 10 to 100 higher levels of the active ingredient compared to mature broccoli. The sprouts have been cooked and blended along with a small amount of radish sprouts. Before you commit to participating, we will have you sample the cream of broccoli sprout soup to help you decide if you want to participate or not.

### **Other information:**

For the inconvenience of providing multiple blood samples, collecting urines and coming to the center every day, you will receive \$500.00 once you have completed the three study periods.

### **Any Questions or Concerns?**

For any questions feel free to call Lisa Levy,  
the study project coordinator  
at (206) 667-6340