

Hello - My name is Dr Carol Ireton-Jones, and I am a Registered Dietitian working with Vytala Health as a Medical Consultant.

We are conducting a study entitled “Application of Seracal™, a medical food, on nutrient absorption in individuals greater than 1 year of age with malabsorption and related diagnoses outside of cystic fibrosis”.

You have the consent form for the study - In this consent form, “you” refers to the study participant. If you are a parent or guardian, please remember that “you” refers to the study participant.

Seracal is a medical food that provides pre-digested (broken down) fat, in a powdered form. It contains essential fatty acids, monoglycerides, and choline-containing phospholipids (lecithin). The most important benefits that you may expect from taking part in this research include improving your body weight, absorption of digested fats, improvement in essential fatty acid levels and decrease in GI symptoms, however, there is no guarantee, and your condition may stay the same. There are no risks that have been identified with consuming Seracal in previous studies.

The purpose of this study is to examine over a two-week period, the effect of Seracal on body weight, reported GI symptoms and product acceptance. I am the Principle Investigator for this study which means that I will obtain your consent, and I will make sure that all the data is collected and reported appropriately.

Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled. Possible benefits to others include sharing the data collected so that others can consider using the product.

Please read the consent form which has the answers to questions you might have like – how long you will be in this study – the answer is your taking part in this research will last 2 weeks.

If you decide to take part in this research study, you will consume Seracal and complete some forms.

Consumption of Seracal daily for two weeks.

- Dosing: Patients aged 1-11 a total of 2 doses or servings per day and ages 12 and above a total of 3 servings/doses per day.
- One serving/dose = approximately ¼ cup/4 tbsp of powder (or 13.4gm when weighed) The total will be ½ cup/day for participants ages 1-11 and ¾ c per day from age 12 and up
- Seracal should be mixed with acceptable food and consumed with meals and snacks – we have a video and lots of recipes to share with you!

Forms to complete:

- You will complete a simple diet recall form before and after the trial,
- record your daily intake and other notes,
- record your starting weight, mid-point and ending weight.
- complete a GI symptoms form, initially and at the end of 2 weeks.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

Vytala, the manufacturer of Seracal, will provide a 2-week supply of Seracal to each patient at no charge. At the end of 2 weeks, each study subject may request a complimentary additional week's supply if you wish to continue. Vytala Health will provide no financial incentive to the patient's referring physician or the patient for participation in this data collection study.

Instead of being in this research, Seracal is currently available with a prescription to be purchased. It may be covered by insurance.

To obtain Seracal for regular use, Vytala has partnered with Pentec Health to assist with ordering and reimbursement questions.

After you have read the consent form and have no further questions, please sign the form (in-person or via the on-line signature option). I will sign it as well via DocuSign and send a copy to you.

You will be contacted to let you know when to expect your first Seracal shipment!