

How long is this study?

You will be followed for up to one year from the time you started the study.

Can I stop participation in the study?

Your participation in this study is voluntary. You may refuse any follow-up data collection phone calls or contacts at any time for any reason. This will not affect your medical care.

How will this study benefit me?

This study has the potential to help doctors learn which treatment to offer to their patients with MBO to give them the best quality of life and to help them avoid hospitalization.

We are committed to providing care and support to you. We hope to make this study as easy as possible for you and your family by collecting information by phone about your food intake and your quality of life.

Thank you for considering this study.

If you have questions or would like to be part of this study, contact the research staff at:

SI316

The Malignant Bowel Obstruction Study

Evaluating the Impact of Surgical versus Non-Surgical Treatment of Malignant Bowel Obstruction (MBO) on Quality of Life, Symptoms, and Food Intake – a clinical research study.

Evaluating Malignant Bowel Obstruction (MBO)

Malignant bowel obstruction is a common problem for patients with advanced abdominal or pelvic cancers. You are being asked to consider this study, a clinical trial, because you have been diagnosed with malignant bowel obstruction.

What is Malignant Bowel Obstruction?

Malignant bowel obstruction (MBO) is the blocking of the progress of food and fluids through the stomach and colon. MBO is a common problem in patients who have abdominal or pelvic cancers, such as cancer of the colon, the ovaries, or the stomach. The bowel obstruction can be partial (some food can pass through) or complete (no food can pass through). There may be single or multiple obstructions.

How is MBO treated?

There are currently two standard treatments for MBO. These are surgery or a non-surgical approach using medications.

Why study MBO?

Even though MBO is a somewhat common diagnosis in patients with abdominal or pelvic cancers, there are no simple treatment guidelines for doctors to follow. We are doing a study to determine whether surgery will improve an MBO patient's quality of life, or whether the surgery provides little benefit. Since the ability to eat and drink easily is very important to quality of life, we want to understand how surgery affects what patients are able to eat and drink.



What would I be asked to do?

You and your doctor will discuss the options available to you. They will determine a treatment plan intended to give you the best quality of life during your cancer care.

To be a candidate for the Malignant Bowel Obstruction study, you must agree to random assignment by the study to surgery or medical management. Randomly assigning patients to one of two treatments being compared can help make study results more reliable.

Your team will review your medical record to collect information from your most recent physical exam, blood draw, and CT (computed tomography) or MRI (magnetic resonance imaging) scan. You will then receive treatment. During the 12 months following your treatment, someone from the study will call you regularly to ask you questions.

Weekly phone calls: Once a week for 13 weeks, a Malignant Bowel Obstruction Study team member from your local study site will call you. He or she will ask you questions from two quality of life questionnaires. You will also be asked to provide some information about any hospitalization and any malignant bowel complications you may have experienced. These calls are expected to take 20 to 30 minutes. After 13 weeks, you will be asked to complete only one questionnaire every 4 weeks for up to one year from the date you started the study. Only you may answer the quality of life questions, but you may ask someone else (for example, a family member involved in your care) to answer the other questions. These calls are at no cost to you.

Monthly phone calls: Once a month, you will get a call from a staff member from the Arizona Diet, Behavior, and Quality of Life Assessment Lab, which is helping with this study. He or she will ask you about your food and drink intake during the past 24 hours. You will be asked about the frequency of your meals, any use of feeding tubes and formulas, and any foods that you avoid and why. These calls are expected to take about 15 to 20 minutes. The first call will be about 7 days after you start the study. Then you will get a call every 4 weeks for up to one year from the date you started the study. You or someone who helps with your meals may respond to these phone calls. These calls are at no cost to you.

The study staff will give you a calendar to help keep track of these weekly and monthly calls. If at the time of a call, you do not feel up to answering the questions, you may ask the caller to reschedule the call.