

Learn about a clinical study for people on parenteral nutrition (PN)

What is the goal of this clinical study?

The goal of this clinical study is to learn whether adding investigational **intravenous (IV) Choline Chloride** to regular PN infusions can help people ages 12 years and older living with intestinal failure.

The main goals are to learn:

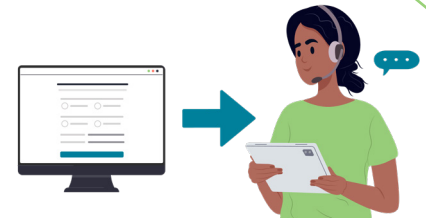
- About the **safety** of different doses (amounts) of IV Choline Chloride and what happens to it in the body. This could help researchers choose doses of IV Choline Chloride to use in the future.
- How well IV Choline Chloride **works** to raise choline levels.



Could I join this study?

You (or your loved one) may be able to join this study if you:

- Are at least 12 years old
- Have intestinal failure
- Have used PN at least 3 times a week for at least 6 months
- Are not taking medicines or certain supplements that affect your liver health



The study staff will talk with you about other criteria that you must meet to join the study.

What is IV Choline Chloride?

IV Choline Chloride is a study drug. It is liquid choline given through a vein (intravenously) with PN infusions by adding it directly into the PN bag, or adding it into a normal saline bag.

If you join the study, you will get IV Choline Chloride at some point during the study.

What is choline and why is it important?

Choline is an essential nutrient, like vitamins. Your body needs choline to work as it should.

Past studies have shown that **almost 8 of 10 people on PN have low levels of choline**. Low choline levels can keep your liver, brain, nerves, muscles, and bones from working properly.



What will happen during this study?

You will be in the study for about a **year and a half** and have up to:

- 12 visits to the study site, and
- 5 visits at your home

You may have more visits, if needed, for study staff to check your health.

Here is what will happen during the study:



You will first sign an informed consent form (ICF) to join the study.

After that, the study staff will ask questions and do some tests to be sure you can be in this study, which is called screening.



Once you are in the study, the study staff will train you on how to add your assigned study drug to your PN at home.

You will have to keep a diary and take photos when you prepare and add the study drug to your PN infusions.



You will have tests, including:

- Physical exams
- Blood and urine tests
- Imaging tests, such as MRIs of your liver
- Heart tests called ECGs
- Questions about your diet

Will I have any costs or be paid?

You will not have any costs for being in the study.

You may be paid back (reimbursed) for certain costs related to the study, such as time and travel costs for study visits.

How can I learn more and join the study?

To learn more about this study, visit the website below or scan the QR code:

thrive3study.com



To see if you or your loved one can join, please scan the QR code:

