

WHAT ARE CLINICAL RESEARCH STUDIES?

Clinical research studies help scientists and doctors explore whether a medical strategy or drug is safe and effective for people. Clinical research studies are important because they help identify which medical approaches work best for certain illnesses in certain groups of people.

There is no guarantee that the study medication will improve your ITP, but what researchers learn from the LUNA 3 study may lead to better medications in the future.

If you have questions or would like to learn more about the LUNA 3 study, please contact the Principal Investigator, Dr. Michele Lambert at (215) 590-4667 or the Study Coordinator, Abinaya Arulselvan at (215) 590-3582 or arulselvaa@chop.edu

YOU CAN HELP ADVANCE ITP RESEARCH

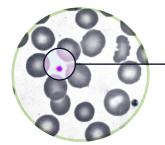
Learn about the LUNA 3 study and a potential new medication for people with primary immune thrombocytopenia (ITP).

WHAT IS THE LUNA 3 STUDY?

The LUNA 3 study is for teenagers and adults (ages 12 and up) with primary immune thrombocytopenia (ITP) for which standard medications are no longer working. The goal of the study is to see if the study medication can safely increase platelet counts and improve symptoms for people with ITP. Researchers will also examine how long these effects last.

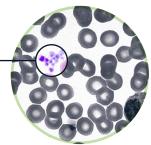
Platelets and ITP

Platelets are our smallest blood cells. When people are injured, platelets help stop bleeding by forming clots, or clumps. People with ITP have very low levels of platelets because the body's immune system destroys them. The study medication in the LUNA 3 study is designed to prevent the immune system from destroying platelets.



Low platelet count Very few platelets exist with other blood cells

Normal platelet count A lot of platelets exist with other blood cells





WHO CAN JOIN THE STUDY?

You may be able to join the study if you meet the following study requirements*:

- 12 years of age or older
- Diagnosed with primary ITP
 - For at least 6 months for ages 12 through 17
 - For at least 3 months for ages 18 and up
- Have taken IVIg or steroids, but they are no longer working
- Have platelet counts of less than 30,000
- * Other study requirements will apply.

WHAT IS THE STUDY MEDICATION?

The study medication is called rilzabrutinib. It is an investigational medication designed to stop your immune system from destroying your platelets. Investigational means that the study medication has not been approved by the U.S. Food and Drug Administration (FDA), or the regulatory administration in any country, to use outside of clinical research.

WHAT CAN PATIENTS IN THE STUDY EXPECT ?

If you qualify and join the LUNA 3 study, your study participation will last about 1 year. You can expect the following:

- Be randomly assigned by a computer to receive either the study medication or placebo (which has no active ingredients). You will swallow 1 pill twice daily. About 1 out of 3 patients will receive placebo in the first part of the study, but everyone will have the option to receive the study medication later in the study.
- Report to the study doctor's office for visits about every 4 weeks for about 1 year for tests and exams, such as physical exams, heart tests, and blood test.
- Have blood drawn weekly. This may be done at the study doctor's office or at home by a healthcare professional (if this service is available where you live).

If the study medication improves your platelet counts, you may qualify to participate in an extension of the study, in which you will receive the study medication for an additional year. During that year, patients will visit the study doctor's office monthly.