

Thank you for your interest in this study.

If your child is being treated for anemia due to CKD, please consider the 1517-CL-1003 Study.

This study is testing an oral medicine in children age 2 through under 18 years of age with anemia due to CKD.

Please talk with a research team member to learn more.

For more information about the 1517-CL-1003 Study, please contact:

[Insert Research Contact Information]

 **1517-CL-1003**
STUDY

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A Clinical Research Study
for Children and Adolescents
with **ANEMIA** Due to

CHRONIC KIDNEY DISEASE (CKD)

**Learn more about a study medicine
that aims to treat this condition**



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About the 1517-CL-1003 Study

This study is evaluating an oral medicine called roxadustat to see if it is safe and effective for treating children with anemia (low levels of red blood cells) due to chronic kidney disease (CKD).

Roxdustat is designed to improve anemia by increasing hemoglobin (a protein found in red blood cells that carries oxygen through the body) levels in the blood.

What are the benefits of participation?

Participants may receive at no cost:

- ◆ Access to study medicine for up to 12 months
- ◆ Close care and monitoring from the study doctor
- ◆ Reimbursement for travel expenses

There is no chance of receiving a placebo in this study. All participants will receive the study medicine (roxadustat).

A placebo is an inactive substance that looks like the study medicine that is sometimes used in clinical research.

Who can join the 1517-CL-1003 Study?

To join this study, patients must be:

- ◆ age 2 through under 18 years old,
- ◆ diagnosed with anemia due to CKD

Children on dialysis may also be able to join this study.

The study team will discuss all of the requirements with you to see if this study is a good match for you and your child.

How long is the study?

This study will last up to 60 weeks (approximately 1 year and 2 months) with up to 17 visits to the study site.

The study includes three periods:

The screening period:

Lasts up to **4 weeks**

The treatment period:

Lasts up to **52 weeks**

The follow-up period:

Lasts up to **4 weeks**

About clinical research studies

A clinical research study (also called a clinical trial) involves supervised research that is required before a medication can be made available to the public.

- ◆ Clinical trials follow strict rules to protect the rights, safety, well-being, and privacy of all participants.
- ◆ Trial results may help determine if a medication is safe and effective in adults and children.
- ◆ Clinical trials are the only way to develop new medications to improve healthcare for future generations.

Children under the legal adult age require a parent or legal guardian to provide consent (or approval) for their study participation.

Taking part in a clinical research study is a very personal choice. Patients can end their study participation at any time, for any reason, without it affecting their medical care or health insurance, now or in the future.

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