

Protocol Plain Language Summary

A clinical study of posaconazole in children (MK-5592-127)

Protocol Title: A Phase 2, Open-Label, Single-Arm, Sequential-Panel Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of Posaconazole (POS, MK-5592) Intravenous and Powder for Oral Suspension Formulations in Pediatric Participants From Birth to Less Than 2 Years of Age With Possible, Probable, or Proven Invasive Fungal Infection

Why is this study needed?

Researchers are looking for new treatments for fungal infections in children. **Fungal infections** are infections caused by a fungus, such as yeast or mold. The most common fungal infections in children are yeast infections on the nails, skin, genitals (vagina or penis), and mouth (called thrush). There are also some serious fungal infections that happen inside the body, such as the lungs.

Researchers designed a study medicine called **posaconazole** to treat serious fungal infections inside the body. Posaconazole can be given to people in different ways.

The goal of this study is to learn about the safety of posaconazole in children and how well children tolerate it. Researchers will learn what happens to posaconazole in a child's body over time when given through a needle into a vein as an intravenous (IV) infusion and when taken as a liquid by mouth.

Who will take part in this study?

About **40 children** with fungal infections will be in this study. They will:

- Be less than 2 years old
- Weigh more than 500 grams (about 1 pound)
- Not have certain lung conditions or a current COVID-19 infection

What treatments are being given during this study?

During the study, children will receive:

- **Posaconazole**, the study medicine

All children will receive posaconazole as an IV infusion. Some children will also take posaconazole as a liquid by mouth.

How is this study designed?

There will be 2 parts to this study and each child will be in 1 part:

Part 1: Children will receive posaconazole 1 time as an IV infusion. Researchers will watch the children for 2 weeks. They will check for safety concerns before deciding to start Part 2 of the study.

Part 2: Children will receive posaconazole for up to 3 months. All children will receive posaconazole as an IV infusion 2 times on day 1, then 1 time a day for at least 6 more days.

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Then, children will either:

- Continue to receive posaconazole as an IV infusion 1 time a day.
- Take posaconazole as a liquid by mouth 1 time a day for at least 7 days. Then, they may switch back to receive posaconazole as an IV infusion 1 time a day or continue to take posaconazole by mouth.

The researchers and the children's parents or caregivers will know which study treatment a child is getting (**open-label study**). During the study, children will give blood samples, have physical examinations, and have heart tests (electrocardiograms or ECGs).

A child will be in the study for up to 4 months.

What are the goals of this study and how will they be measured?

Main goal	How it will be measured
To learn what happens to posaconazole in a child's body over time	Researchers will measure the amount of posaconazole in children's blood samples at different times during the study
Other goals	How they will be measured
To compare what happens to posaconazole over time in a child under 2 to people older than 2 years	Researchers will measure the amount of posaconazole in children's blood samples at different times during the study. They will compare this to the amount from older children and adults in other studies.
To learn about the safety of posaconazole and how well children tolerate it	During the study, researchers will measure the number of children who: <ul style="list-style-type: none"> • Have an adverse event (AE) – an AE is a health problem that happens or worsens • Stop treatment due to an AE • Have an AE that researchers think could be related to the treatment received during a study
To learn the survival of children who receive posaconazole	Researchers will measure the number of children in Part 2 who die by 1 month
To learn if children need more treatments for the fungal infection	Researchers will measure the number of children in Part 2 who receive more treatments for the fungal infection (other than posaconazole)

What are the possible benefits and risks?

Clinical studies may have benefits and risks. Children may benefit because the study medicine may treat the fungal infection or stop it from getting worse. There may be risks because the study medicine may not work or may cause health problems.

This study has a group of experts, separate from the researchers, that oversee the benefits and risks. If they decide that the study medicine is not safe or doesn't show benefit, the study can be stopped. More information about the benefits and risks is in the protocol.