Summary of Results for Laypersons

Astellas is grateful to the parents and babies who took part in this clinical study. Thank you.

What was the Study Called?

Pharmacokinetic, Safety and Tolerance Study of Three Doses of FK463 in Premature Infants

Why was this Study Needed?

When babies are in the hospital they are at risk for getting fungal infections. One reason for this risk is the use of antibiotics. Another is when doctors puncture, open or cut the skin for a procedure. There is also a risk of getting a fungal infection if the baby's immune system is not working well. This is especially true for premature babies.

Fungal infections can be caused by a yeast called *Candida*. If the infection with *Candida* has spread throughout the body it is called systemic candidiasis. When it is in the blood it is called candidemia. There was a need to find new treatments for premature babies who are at risk of getting a fungal infection.

In this study, researchers wanted to learn how micafungin moved through the bodies of premature babies. This would help researchers work out the best dose and how often micafungin should be given.

Also, researchers wanted to learn if these premature babies had any unwanted effects from micafungin.

The study started in January 2001 and ended in June 2002. The sponsor of this study (Astellas) reviewed all the study information and created a report of the results. This is a summary of that report.

What Kind of Study was this and Who Took Part in It?

This was an "open-label" study. "Open-label" means that each patient and a study doctor know which medicine that patient received. In this study, the parents of each baby and the study doctors knew that the baby received micafungin.

This study included the following premature babies:

- Babies with a postconceptional age of less than 40 weeks. "Postconceptional age" means the number of weeks of pregnancy plus the number of weeks after birth. This is usually how the age of premature babies is reported.
- Babies who weighed 500 grams (1.1 pounds) or more.
- Babies who were already receiving treatment for fungal infections.

When each baby joined this study, the study doctors placed that baby in 1 of 2 weight groups:

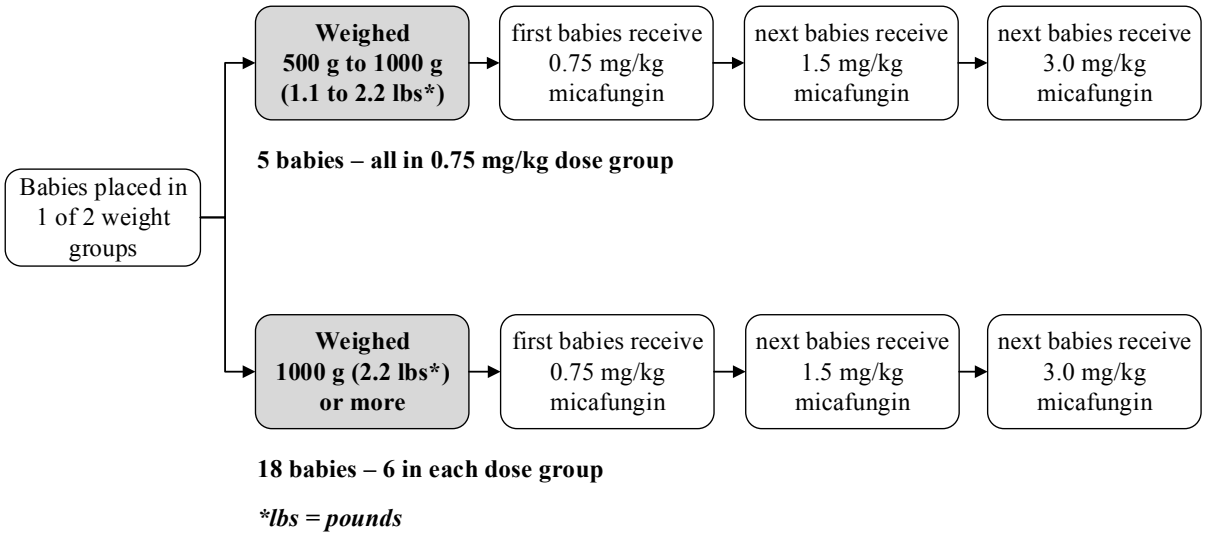
- Babies weighing between 500 grams and 1000 grams (between 1.1 and 2.2 pounds)
- Babies weighing more than 1000 grams (2.2 pounds)

In this study, each baby received 1 dose of micafungin given slowly over 30 minutes. A few small blood samples were taken from each baby up to 24 hours after they received this dose of micafungin.

Study doctors gave higher doses of micafungin to different small groups of these babies, starting with the lowest dose. Babies from each weight group were dosed separately.

Babies received milligrams (mg) of micafungin for each kilogram (kg) of their body weight. This is also known as mg/kg micafungin.

Dosing by Baby Weight Group



For each group of babies, the study doctors checked for certain unwanted effects after each dose. The doctors checked babies from each weight group separately. If there were no severe unwanted effects in each weight group, then the next group of babies in that weight group could receive the next dose of micafungin.

Also for each group of babies, the study doctors checked the amount of micafungin in the blood from the babies after each dose. Again, the doctors checked babies from each weight group separately. From this, researchers could work out how micafungin moved through the bodies of the babies.

This study took place at 8 clinics in the US. 23 babies were in the study and received micafungin.

	Number of Babies
Age Group A postconceptional age of 26 to 39 weeks. Postconceptional means the number of weeks of pregnancy plus the number of weeks after birth.	23
Sex Boys Girls	 14 9

What Were the Study Results?

5 babies weighed between 500 and 1000 grams (1.1 and 2.2 pounds). Of these:

- 5 babies received 0.75 mg/kg of micafungin.

No more babies in this weight group joined the study. Therefore babies in this weight group did not receive higher doses of micafungin.

18 babies weighed more than 1000 grams (2.2 pounds). Of these:

- 6 babies received 0.75 mg/kg of micafungin
- 6 babies received 1.5 mg/kg micafungin
- 6 babies received 3.0 mg/kg micafungin

How did micafungin move through the bodies of premature babies?

The answer to this question helped researchers work out the best dose and how often micafungin should be given. Researchers checked the blood samples taken from the babies after the babies received micafungin. This was done for the 3 different doses.

In this study, researchers learned that micafungin moved through the bodies of premature babies in a similar way to those of young children. The only difference was that micafungin left the body quicker in premature babies than it did for younger children.

What Adverse Reactions did Babies in this Study Have?

A lot of research is needed to know whether a medicine causes a medical problem. So when new medicines are being studied researchers keep track of all medical problems that patients have while they are in the study. These medical problems are called "adverse events" and are recorded whether or not they might be caused by the treatment taken. An "adverse reaction" is any medical problem or "adverse event" that is judged by the study doctor to be possibly caused by a medicine or treatment used in the study.

1 baby (4.3%, or 1 out of 23 babies) had an adverse reaction in this study. This baby had a decreased blood level of potassium.

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems or needs hospital care. None of the babies in this study experienced a serious adverse reaction in this study.

Where Can I Learn More About This Study?

This document is a short summary of the main results from this study. You can find this summary and more information about this study online at http://www.astellasclinicalstudyresults.com.

Please remember that researchers look at the results of many studies to find out how well medicines work and which adverse reactions they might cause. This summary only shows the results of this 1 study. Your baby's doctor may help you understand more about the results of this study.

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