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WINN FELINE FOUNDATION

Currently Enrolling Cats:
Efficacy of a New Drug for Treatment of Cats with Ronidazole-Resistant *T. foetus* infection

PURPOSE OF STUDY

The purpose of this study is to determine if a new drug is able to safely and effectively treat *Tritrichomonas foetus* infection and diarrhea in cats that have previously failed treatment with ronidazole. Currently there are no alternatives to ronidazole for treatment of cats with *T. foetus* infection.

IMPORTANCE OF STUDY

Tritrichomonas foetus was first described 20 years ago. The infection causes a foul diarrhea that is debilitating in kittens and can persist unrelentingly for up to 2 years. The infection is enduring and results in relapsing bouts of diarrhea throughout life. Cats in every corner of the world are afflicted by *T. foetus* infection and untold numbers of these cats can never be cured. Despite many attempts to identify an effective treatment for *T. foetus*, only ronidazole has been identified as capable of eradicating the infection. Unfortunately, ronidazole can cause neurotoxicity in cats and 36% of treated cats fail to clinically benefit from the drug. In the near future, new FDA guidelines will likely prevent veterinary pharmacies from further compounding of unapproved bulk-chemical drugs such as ronidazole. Therefore there is a critical need to identify safer, more effective, and FDA-approved drugs to eradicate *T. foetus* infection in cats. Without such a drug, *T. foetus* will continue its worldwide spread and plague cats and their owners with chronic incurable diarrhea.

ELIGIBILITY CRITERIA

To be eligible for participation in the study your veterinarian will need to confirm that your cat has been treated with a recommended dose and duration of ronidazole, still has clinical signs of diarrhea, and establish the continued presence of *T. foetus* infection by performing a PCR test on a fecal sample. Your cat will need to undergo a complete physical examination by your veterinarian and have a blood and urine sample submitted to establish that there is no evidence of concurrent systemic disease.

REQUIREMENTS FOR PARTICIPATION

If your cat qualifies and in order to participate in the study you will be required to do the following:

1. Keep your cat confined from other cats during the entire 3 week duration of the study.
2. Keep a daily log in which you will record the number of bowel movements and score the consistency of your cat's feces and answer general questions about the health and any evidence of adverse effects of drug administration.
3. Administer drug as prescribed orally once a day for 7 days.
4. Return your cat to your veterinarian on days 7, 14, and 21 of the study. On these visits a blood and urine sample will be obtained to look for any evidence of adverse drug effects. Feces will be collected from your cat by passing a thin, red-rubber tube through the anus into the colon (a video of this procedure can be viewed at www.youtube.com/watch?v=JMfZ9M80V8E).
5. If your cat tests negative for *T. foetus* infection on days 14 and 21 of the study, you must be willing to administer a laxative to your cat for 3 days and then return your cat to your veterinarian for a final fecal collection.

POSSIBLE RISKS

The drug is an orally-administered compound that used to be prescribed to people and in some cases dogs for treatment of rheumatoid arthritis. The drug has recently been recognized as effective in killing various types of protozoal pathogens and is effective in killing feline *T. foetus* in the laboratory. The drug has never before been administered to cats. Whether or not the drug is potentially toxic to cats is unknown. In people, the most common adverse effect of the drug is diarrhea that resolves when the drug is withdrawn. Less frequent adverse effects include rash, itchiness, bone marrow suppression, and protein in the urine. Because the drug has not been used in cats, it is possible that other unknown adverse effects might occur. While it is very unlikely, these bad reactions could even be fatal.

POSSIBLE BENEFITS OF PARTICIPATION

The potential benefits can be divided into three areas; benefit to you, to your cat, and to veterinary medicine (and therefore to the benefit of all cats and the people that love them).

Benefit to you: This study will pay for all costs associated with treatment of your cat and monitoring for adverse drug effects. You will be responsible for all costs associated with treatment of any adverse drug events that could happen to your cat.

Benefit to your cat: Because cats participating in this study have failed treatment with ronidazole, there currently exists no other options for treatment of the *T. foetus* infection or diarrhea. It is possible that participation in this study will eliminate *T. foetus* infection from your cat.

Benefit to veterinary medicine: By allowing your cat to participate in this study, you are an integral part of our ability to evaluate a possible treatment for what is otherwise an incurable disease. If the new drug proves useful, the importance of this knowledge is obvious. However, if the drug proves not to be useful, that information is every bit as important. Efforts can be shifted to other potentially effective new drugs.

VOLUNTARY PARTICIPATION

Participation in this study is voluntary. You may decide to withdraw at any time.

COMPENSATION

You will be responsible for all costs incurred in treating your cat for any adverse drug effects resulting from treatment with the drug. You will not be charged any additional fees if you participate in this study.

CONFIDENTIALITY

All information obtained in this study will be considered confidential and used only for research purposes. The identity of any individual animal in the study will be kept confidential when results of the study are presented, unless you are contacted and provide written authorization to do otherwise.

CONTACT PERSON FOR THE STUDY

To obtain more information regarding this study contact:
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