

30 NOV 2017

Column E Explanation

1. Registration Number
 - a. 51-F-0024
2. Number of animals used in this study.
 - a. Column E = 20
3. Species of animals used in this study
 - a. Hamster
4. Explain procedure producing pain and/or distress.
 - a. Hamsters are injected with infectious *L. donovani*, observed weekly until the 5th wk. Then they will be observed daily for evidence of severe infection by blood samples or physical appearance. A severe infection causes swelling of the liver and spleen which is noticeable as a swollen abdomen. The animal also becomes lethargic. These symptoms appear after 2 months with an effective inoculation with a fully virulent strain. The laboratory strain in use in our studies requires at least 4 months before symptoms become apparent. Before the animals exhibit severe discomfort they will be sacrificed, exsanguinated, spleens removed by dissection and parasites recovered from spleens. The mortality rate due to parasite infection varies with the virulence of the strain injected. In our experience from studies in the past three years, the Ld1S strain, when maintained in hamsters, is nearly 100% fatal by 4 -6 months after infection. The live attenuated strains to be developed as part of this study are not expected to cause disease or to be fatal. The study evaluating the potential for long-term pathogenicity of the attenuated strains will maintain the infected animals for up to 12 months as long as no disease symptoms are apparent.
5. Attach or include an explanation with the reason/s for why anesthetics, analgesics and tranquilizers could not be used.
 - a. The use of drugs and analgesia would not be effective and would complicate interpretation of the results. The experiments endpoints are based on years of experience with this model and need for the animals to develop advance disease to see if the experimental vaccine is effective.
6. What, if any, federal regulations require this procedure?
 - a. N/A