Exhibit A

MILLER
SCHOOL OF MEDICINE
UNIVERSITY OF MIAMI

Department of Dermatology and Cutaneous Surgery
Wound Healing Research Laboratory

Pilot Study Protocol

Effects of Revity on Dermatophytes Using a Porcine Model

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SPONSOR

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SPONSOR RESPRESENTATIVE

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INSTITUTIONAL POLICIES AND REGULATIONS

The following experiment will be submitted for approval by University of Miami's Animal Use Committee. This study will be conducted in compliance of the University of Miami's Department of Dermatology & Cutaneous Surgery's Standard Operating Procedures (SOPs). Animal will be monitored daily for any observable signs of pain or discomfort. In order to help minimize possible discomfort, two analgesics (buprenorphine and fentanyl transdermal patches) will be used.

OBJECTIVE

The objective of this study is to assess the ability of Revity to reduce dermatophytes in normal skin. We will quantify the amount of each microorganisms removed from infected skin.

MATERIALS AND METHODS

Experimental Animals

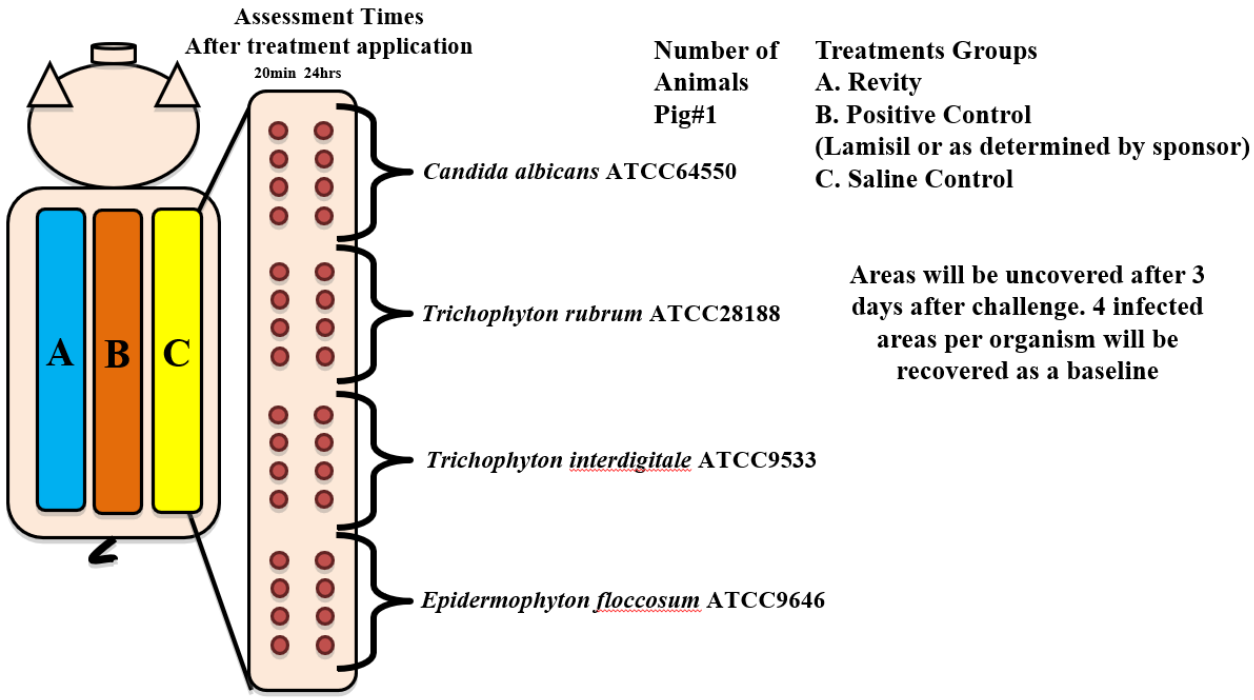
A porcine model will be used for our experimental research due to the morphological similarities between swine skin and human skin. [1] One (1) animal will be used for this study. The young specific pathogen free (SPF: Looper Farms, North Carolina) pigs weighing 35-45 kg will be kept in house for at least 5 days prior to initiating the experiment. The animal will be fed a basal diet *ad libitum* and will be housed individually in our animal facilities (meeting American Association for Accreditation of Laboratory Animal Care [AAALAC] accredited) with controlled temperature (19-21^{o}C) and lighting (12h/12h LD).

Procedure Technique

The back of the experimental animal will be clipped with standard animal clippers on the day of the experiment. The skin on both sides of the animal will be prepared by washing with a non-antibiotic soap (Neutrogena Soap Bar; Johnson and Johnson, Los Angeles, CA) and sterile water. Each animal will be anesthetized and given analgesics till the end of the study.

One hundred and twelve areas (12 mm) will be inoculated as described below. Special Finn Chambers will be used to hold the inoculum in place. The areas will be separated from one another by 2-3 cm of normal skin.

Figure 1: Experimental Design



Areas Inoculation

Pathogenic strains of *Candida albicans* ATCC64550, *Trichophyton rubrum* ATCC28188, *Trichophyton interdigitale* ATCC9533 and *Epidermophyton floccosum* ATCC9646 will be used in this study. All microorganism's inoculum suspensions will be made by swabbing a 3-cm diameter area of the growth from a culture plate into 4.5 ml of sterile water. This will result in a suspension consisting of approximately 10^{10} colony forming units/mL (CFU/mL). One ml of this suspension will be diluted into 35 ml of Tryptic Soy Broth (TSB), making the inoculum suspension 10^{6} CFU/ml. A sample of this suspension will further be diluted and plated onto culture media to enumerate viable CFU/ml of organism prior to the experiment. The inoculum suspension will be used directly to

inoculate each area by pipetting a 25 µl aliquot into each chamber and then put in contact with unwounded skin. All areas will be covered with a Finns Chambers for 72 hours to allow colonization. Patches will be secured with surgical tape and wrapped with Coban elastic wrap (3M, St. Paul MN).

Treatment Regimen

After 72 hours of infection (Day 0 of treatment) the chambers will be removed, and 4 infected areas will be recovered as a baseline. The remaining areas will then be randomly assigned one of the following treatments groups: A) Revity, B) Positive Control [Lamisil or as determined by sponsor] , or C) Untreated control (Figure 1 above). The Revity treated area will receive approximately 200 ul of treatment and will be allowed to remain in place for 30 seconds. The positive control will be kept on as manufacturer recommendation. The Saline control will receive Saline for 30 seconds. The Revity and Saline treatments will then be rinsed with a 5ml syringe with sterile saline followed by wiping the area with sterile saturated gauze. All treatments will be applied only once. Within 20 minutes of treatment 4 areas will cultured as described below. The remaining areas will be individually covered with a polyurethane film dressing (Tegaderm, 3M, St. Paul MN: Figure 1 above). All dressings will be secured in place with tape and covered with Coban wrap (3M, St. Paul MN).

Erythema Measurements

During each assessment time the amount of erythema (redness) around the area will also be clinically scored.

Erythema – indicative of the amount of inflammation present*
* Score: 1 = absent, 2 = mild, 3 = moderate, 4 = marked, 5 = exuberant

Microbiology Assessment

On day 0 (72 hours after inoculation) four areas will be biopsied (6 mm) as a baseline. Then four treated areas will be biopsied (6mm punch biopsy) after 20 minutes for each treatment. The remaining areas will be cultured at 24 hours.

The biopsies (6mm) will be weighed and immediately placed in 1 ml of All Purpose Neutralizing Solution. The sample will be combined with an additional 4 ml of Neutralizing Solution and homogenized in a sterile homogenization tube. Serial dilutions (Figure 2 photo **a**) will be made from all culture samples and the extent of microbiological contamination assessed using the Spiral Plater System (Spiral Biotech, Norwood, MA – photo **b**). This system deposits a 50µl aliquot of the scrub bacterial suspension over the surface of a rotating agar plate. BBL™ CHROMagar™ Candida will be used to isolate C. albicans and either BBL™ Sabouraud Dextrose Agar or Difco™ Potato Dextrose Media will be used to isolate the other 3 dermatophytes (*Trichophyton rubrum* ATCC28188, *Trichophyton interdigitale* ATCC9533 and *Epidermophyton floccosum* ATCC9646). All plates will be incubated aerobically (24 hours – 5 days) at 30°C, after which the number of viable colonies will be counted.

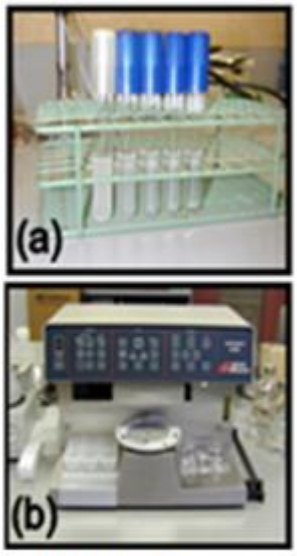


Figure 2
(a) Serial dilutions
(b) Spiral Plater

Histological Assessment

One biopsy (4mm) will be taken from one treatment area at 20 minutes and 24hours after treatment. These specimens will be placed in formalin and sent to sponsor.

DATA ANALYSIS & REPORT TO SPONSOR

Data will be combined, and a report will be sent to the sponsor, which will include interpretation of the data.

REFERENCES

[1] Sullivan TP, Eaglstein WH, Davis SC, and Mertz PM. The pig as a model for human wound healing. Wound Repair and Regeneration 9, 2, 2001, 66-76