

Title: A Randomized, Double-blind, Placebo Controlled Efficacy, Safety, and Tolerability Study of up to 20 mL of DFA-02 in Patients Undergoing Abdominal Surgery

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Sponsor: Dr. Reddy's Laboratories, Inc.

Purpose of Research

The purpose of this research study is to find out whether the investigational drug, DFA-02 gel is effective (able to decrease the chance of an infection where the subject's main surgery cut is made) and safe and can be used without producing any serious side effects with patients having abdominal surgery.

With the agreement of the subject's surgeon, the subject is being asked to take part in this research study because they are going to have abdominal surgery that requires the surgeon to make a cut in the lower belly in order to perform the abdominal surgery. One possible side effect of having abdominal surgery is an infection involving the area where the cut is made. The DFA-02 gel or the placebo gel (the gel that does not contain the DFA-02) will be put into the main surgery cut before the surgery cut is closed. The investigational drug, DFA-02, is being used in this study for patients who could possibly get surgical infections. It will be used alongside the usual antibiotics that the subject will receive before, during and after surgery.

DFA-02 is an investigational drug, meaning that it is still being studied in the United States and has not been approved for use by the U.S. Food and Drug Administration (FDA). DFA-02 is a gel that contains two FDA approved antibiotics; gentamicin and vancomycin and will be placed in the cut at the end of surgery. The FDA has not approved the combination of these antibiotics and the gel.

The total duration of the subject's participation will be a maximum of 62 days (about 2 months) and a minimum of 26 days (about 1 month), depending on when the screening visit occur.

Inclusion Criteria:

1. Scheduled to undergo non-emergent abdominal surgery involving a planned incision of 7 cm or greater (hand-assisted laparoscopic surgery is allowed, however a maximum of 100 patients with laparoscopic surgery will be enrolled). List of eligible procedures: left, right or transverse colectomy, segmental/sleeve left colon resection, total abdominal colectomy with ileorectal anastomosis, total abdominal colectomy with ileostomy, total abdominal proctocolectomy, low anterior resection, sigmoid resection, non-emergent Hartmann's procedure, colotomy with polypectomy distal to hepatic flexure, colostomy takedown through laparotomy (not peristomal) incision, ileo-pouch anal anastomosis and abdominal perineal resection of the rectum.
Note: Also allowed are open repair of ventral hernia with a planned incision of ≥ 7 cm, hepaticojejunostomy, choledochojejunostomy, gastrojejunostomy and pancreaticojejunostomy, however a maximum of 100 patients with these procedures will be enrolled;
2. BMI ≥ 20
3. Available for evaluation from baseline until final evaluation at 30 days postsurgery.

Exclusion Criteria:

1. Known history of hypersensitivity to gentamicin or vancomycin, other aminoglycoside antibiotics or the excipients of the study products (soy bean products or sesame oil);
2. Emergency surgery (urgent surgery is allowed if informed consent is obtained and the preoperative study procedures can be performed);
3. Significant concomitant surgical procedure (Note: concomitant appendectomy, cholecystectomy, oophorectomy, and liver biopsy/wedge resection are allowed);
4. Prior laparotomy within the last 60 days of this planned procedure;
5. Planned second laparotomy or abdominal surgical procedure (e.g. colostomy or ileostomy takedown) within 30 days of this planned first procedure;

6. Expectation that a surgical drain will be placed in the incision (Note: Intraperitoneal drains that do not exit through the treated incision are allowed. Also, if during the procedure the surgeon feels a surgical drain is medically indicated it should be done and it will not be considered a protocol violation);
7. Preoperative sepsis, severe sepsis, or septic shock;
8. Abdominal wall infection/surgical site infection from previous laparotomy/laparoscopy or for any reason;
9. Active systemic infection or systemic (oral or intravenous) antibiotic therapy within the 1 week prior to the date of surgery other than specified preoperative antimicrobial prophylaxis (Note: single dose antibiotic therapy for dental or other minor procedures are allowed as is the use of oral non-absorbable antibiotics for preoperative bowel decontamination);
10. Requirement for gentamicin or vancomycin preoperative antimicrobial prophylaxis (Note: systemic antibiotic therapy with gentamicin or vancomycin within 72 hours after surgery should be discussed with the Coordinating Center PI or Medical Monitor);
11. Concurrent systemic or topical use of other potentially neurotoxic, nephrotoxic, and/or ototoxic drugs, such as gentamicin, cisplatin, cephaloridine, kanamycin, amikacin, polymyxin B, colistin, paromomycin, streptomycin, tobramycin, vancomycin, ethacrynic acid, and viomycin, should be avoided;
12. Preoperative evaluation suggests an intra-abdominal process that might preclude full closure of the skin;
13. Ongoing treatment (e.g. chemotherapy, radiation) for non-colorectal cancer;
14. History of significant drug or alcohol abuse within the past year;
15. Serum Creatinine > 1.8 mg/dL
16. Serum Bilirubin > 2.5 times upper limit of normal;
17. Patients who are immunocompromised including but not limited to systemic corticosteroid use or chemotherapy/radiation during the 30 days prior to surgery, organ transplantation, or HIV infection (Note: inhaled corticosteroids are not exclusionary and single dose use of corticosteroids to prevent PONV is allowed.);
18. Known history of hepatitis B or C or HIV;
19. Pregnant or lactating, or if of childbearing potential not practicing a birth control method with a high degree of reliability;
20. Refusal to accept medically indicated blood products;
21. Participation within 30 days before the start of this study in any experimental drug or device study, or currently participating in a study in which the administration of investigational drug or device within 60 days is anticipated;
22. Unable to participate in the study for any reason in the opinion of the Principal Investigator;
23. Postsurgical life expectancy of less than 30 days, in the Investigator's opinion;
24. Expected discharge from the hospital less than 3 days after surgery.