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"A Prospective, Double-Blinded, Randomized Controlled Trial of Dehydrated Human Amniotic-Chorionic Membrane for Incisional Hernia Prophylaxis"

Background: Incisional hernias (IH) are one of the most common postoperative compilations following open abdominal surgery. Approximately two million laparotomies are performed each year in the United States, with approximately 100,000 requiring postoperative incisional hernia repairs. Repair of IHs is vital. An untreated incisional hernia may result in fatal conditions, such as incarceration and bowel strangulation. IH repairs show high failure, with a 14-63% rate of reoccurrence after repair. Many patients require multiple repairs which increases cumulative financial burden. Currently, no standard of care for IH prophylaxis exists. In a previous xenograft animal model and subsequent prospective study of patients that are high-risk of developing IHs, placement of a dehydrated human amniotic-chorionic membrane (dHACM) significantly reduced IH formation by 64% and 88% respectively. In this clinical trial, we aim to demonstrate that a standard abdominal fascial closure and prophylactic placement of dHACM, will reduce IH incidence in high-risk populations for this post-operative complication.

Objective: The purpose of this trial is to rigorously test the hypothesis that dHACM will significantly decrease IH formation in high-risk patients undergoing open abdominal surgery.

Methods: The study design is a prospective, double-blinded, multi-centered randomized controlled trial with two arms: dHACM treatment and control (NCT04417140). Target enrollment is 533 subjects, as determined by study biostatistician Dr. Denise Danos, PhD (LSUHSC-NO). IH is defined as a midline fascial defect and hernia sac > 4mm in diameter. Subjects are recruited by 24 participating surgeons across four study sites in New Orleans, LA. The study inclusion criteria involve patients with a >150% risk of developing an IH following abdominal surgeries with incisions >6 cm as modeled by Basta *et al*. Fascial closure is standardized across all subjects, regardless of trial arm. Subjects are randomized 1:1 in treatment versus control arms. Patients and physicians are double blinded regarding subject randomization. At 6 months post-operation, subjects are evaluated by a blinded evaluator via ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET) scan to determine the presence of an IH, along with the length of the incision and a subjective pain score. Interim data analyses will be performed after the successful follow-up of 142 and 284 patients. Primary analysis is the rate of IH formation in dHACM-treated vs. control subjects. Secondary analysis is the rate of postoperative complications in dHACM-treated vs. control subjects.

Results: As of September 2022, 160 candidate subjects were screened and 181 enrolled in the study. The first interim analysis will be performed after subject #142 undergoes the final 6-month follow-up evaluation.

Future Direction: Additional patient enrollment and subsequent 6-month post-operative assessments are necessary to determine the effectiveness of dHACM in reducing IH formation following open abdominal surgery.