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

Background: Patients undergoing open abdominal surgery face a 3.8 – 15% risk for developing an incisional hernia (IH). In IH, intra-abdominal contents protrude through the abdominal wall, placing patients at risk for bowel obstruction or necrosis, sepsis, and death. Herniorrhaphy is the mainstay of treatment but has a 50% failure rate at 1 year. Prevention of IH formation would reduce patient risk and healthcare cost. However, there exists no standard of care for IH prophylaxis. In a xenograft small animal model and subsequent pilot study of high-risk IH patients, dehydrated human amniotic-chorionic membrane (dHACM) significantly reduced IH formation by 64% and 88% respectively. The dHACM contains key placental components such as an intact extracellular matrix, growth factors, chemokines, and cytokines that promote surgical wound healing process.

Objective: The purpose of this trial is to rigorously test the hypothesis that dHACM can 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 and control (NCT04417140). Target enrollment is 533 subjects as determined by study biostatistician Dr. Denise Danos, PhD (LSUHSC-NO). Interim analyses will be performed after the successful follow-up of 142 and 284 patients. The study inclusion criteria includes a >150% risk of IH after abdominal surgeries with incisions >6 cm as modeled by Basta *et al*. Subjects are recruited by 24 participating surgeons across four study sites. Fascial closure is standardized across all surgeons, regardless of trial arm. Subjects are randomized 1:1 to treatment vs. control arms and are blinded to their treatment arm. At 6 months post-operation, subjects are evaluated by a blinded evaluator via ultrasound for the presence of an IH, defined as >2 mm gap in the abdominal fascia, along with length of the incision and subjective pain score.

Results: As of October 2021, 116 candidate subjects were screened and 75 enrolled in the study. An interim analysis will be performed 6 months after subject #142 undergoes treatment.

Future Direction: Additional patient enrollment and 6-month post-operative ultrasound imaging is needed to determine dHACM effectiveness in reducing IH formation following open abdominal surgery.