

# The New Orleans Hernia Event Reduction, a Novel Indication for Amnion (NO HERNIA) Trial



## Introduction

- Patients undergoing open abdominal surgery face a 3.8 – 15% risk of developing an incisional hernia (IH).<sup>1</sup>
- Herniorrhaphy is used to treat IH but has a 50% failure rate after 1 year.<sup>2</sup>
- There is no standard of care for IH prophylaxis.
- In our xenograft small animal model and pilot study of high-risk patients, dehydrated human amnion/chorion membrane (dHACM) reduced instances of IH by 64% and 88%, respectively.
- dHACM contains an intact extracellular matrix, growth factors, chemokines, and cytokines that promote surgical wound healing processes.

**Research Question: Is dehydrated amnion/chorion membrane (dHACM) a reliable prophylactic treatment for patients that are high-risk for developing an incisional hernia following open abdominal surgery?**

## Methods

- Double-blind, Randomized Controlled Trial: Treatment (dHACM) vs. Control (standard closure) (Figure 1).
- Inclusion: Patients undergoing abdominal surgery with >150% risk of developing an incisional hernia, and incision site >6 cm.<sup>1</sup>
- Target enrollment: 533 patients.
- Primary Outcome: IH development 6-months post-operation defined as >2 mm gap in the abdominal fascia (Figure 2).

## Procedure and Outcomes

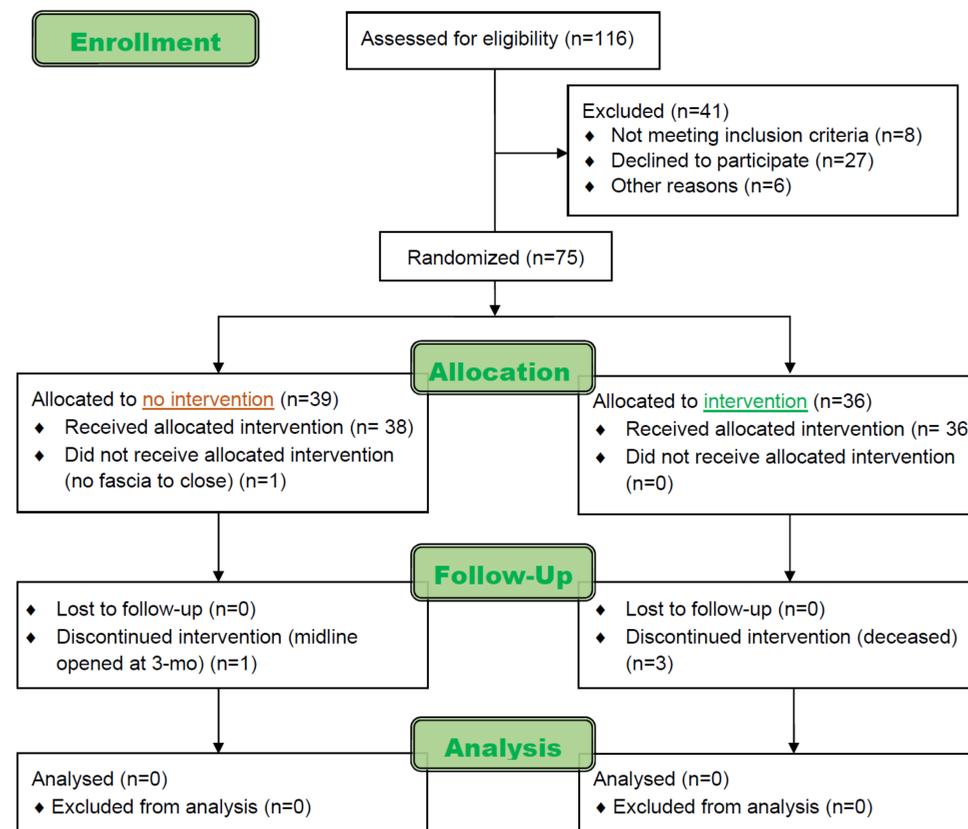


Figure 1. Consort flow diagram of the NO Hernia Trial.

## Primary Outcomes

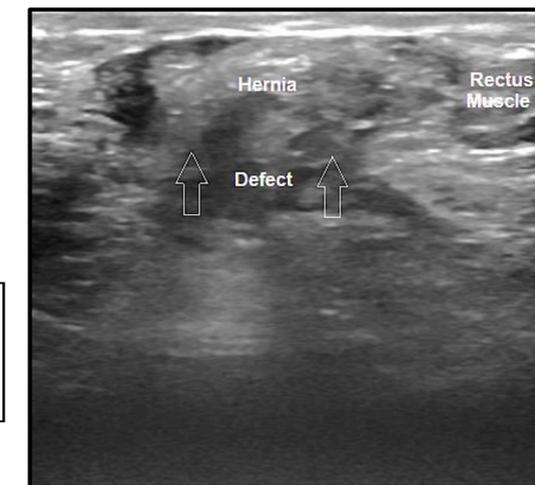


Figure 2. Example of an incisional hernia (>2 mm opening in muscular fascia); Case courtesy of Dr. Sandeep Singh Awal, Radiopaedia.org, rID: 77366.

## Secondary Outcomes

- dHACM effects on post-operative complication rates:
- hematoma, intestinal paralysis, 30-day in-hospital mortality, fistula formation, small-bowel obstruction, and surgical site infection (SSI).

## Summary

- 116 patients screened, 75 enrolled.

## Future Directions

- Additional patient accrual and 6-month post-operative ultrasound imaging is needed to determine dHACM effectiveness in reducing IH formation following open abdominal surgery.
- Interim analysis will be performed after successful follow-ups of patients #124 and #284.

## References

1. Basta MN, Kozak GM, Broach RB, et al. Can We Predict Incisional Hernia?: Development of a Surgery-specific Decision-Support Interface. *Ann Surg.* 2019;270(3):544-553.
2. Luijendijk RW, Hop WCJ, van den Tol MP, et al. A Comparison of Suture Repair with Mesh Repair for Incisional Hernia. *N Engl J Med.* 2000;343(6):392-398.

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