A Minimal-Risk, Multi-Center, Prospective, Clinical Trial to Evaluate the PrevisEA Device for Predicting Gastrointestinal Impairment

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. 18 to 90 years of age 2. having an elective intestinal resection surgery (specific types, study staff will review)

Exclusion Criteria:

1. allergy to skin adhesive 2. unable to have device applied to the skin on the abdomen 3. evidence of infection before surgery, including a deep wound infection or urinary tract infection 4. specific types of surgery (study staff will review)

Conditions & Interventions

Conditions:
Digestive & Liver Health

Keywords:
Clinics and Surgery Center (CSC), Bowel surgery

More Information

Description: This is a minimal risk, prospective, non-randomized, open label, multi-center study designed to assess the performance of the PrevisEA device in the prediction of GII. MH4 levels recorded by the device at 12 hours after placement of the device will provide a prediction of no GII development or GII development within 10 days after the procedure and is based on a previously optimized and validated MH4 cutoff level. PrevisEA is a noninvasive, disposable device that uses audio spectral analysis of sounds produced by the gastrointestinal tract to predict gastrointestinal impairment (GII). GII is most commonly associated with postoperative ileus (POI), but could be the result of other causes, such as early postoperative bowel obstruction. GII is defined as failure of successful early oral re-feeding in a subject undergoing major abdominal surgery. For subjects who are allowed to resume a diet during the first 24 hours after surgery, a failure to successfully orally re-feed a subject is defined as presentation with emesis, requiring a reversal of diet, or the placement of a nasogastric tube on first postoperative day or later. The device is considered non-significant risk (NSR). The device does not inform medical decisions in this study. Researchers will be blinded to results of the device during this study.

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