BSGM to Evaluate Patients With GI Symptoms

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 8 years to 25 years old
Healthy Volunteers: This study is also accepting healthy volunteers
Inclusion Criteria for Cases

1. Males or females age 8 to 25 years.
2. Females ≥11 years of age or who have reached menarche must have a negative urine pregnancy test.
3. Confirmed diagnosis of a Functional Gastrointestinal and/or Motility Disorder OR undergoing one of the following procedures as part of their clinical care at one of the participating centers:
    1. HRVB
    2. PENFS
    3. ADM
    4. Colonic Manometry
    5. Pyloric Botox
    6. Pyloric Dilation
    7. Gastric Scintigraphy
    8. GES
    9. gammaCore
4. Those with a body mass index of < 35.
5. Parental/guardian permission (informed consent) and if appropriate, child assent.

Exclusion Criteria for Cases

1. History of skin allergies or a history of extreme sensitivity to cosmetics or lotions. Currently open wounds, abrasions, infected or inflamed abdominal skin. (Please note, majority of feeding tubes can be accommodated by the array placement.)
2. Pregnant women.
3. Those with any condition, where fasting is not recommended by a physician.
4. Any allergies to foods that may be present in the standardized meal that cannot be accommodated with an acceptable substitute meal.
5. Those with physical limitations, who are not able to maintain a relaxed reclined position for the study visit duration.
6. Those with major developmental delay or cognitive impairment, who are not able to report their symptoms/feelings in the questionnaires.
7. Those with GI motility disorders that are limited in the esophagus, and the gastric mapping is restricted to capture relevant data based on the investigator's discretion.
8. Parents/guardians or subjects who, in the opinion of the Investigator, may be non-compliant with study schedules or procedures.

Inclusion Criteria for Controls

1. Males or females age 8 to 25 years.
2. Females ≥11 years of age or who have reached menarche must have a negative urine pregnancy test.
3. Do not have an active Functional Gastrointestinal disorder (FGID) diagnosis and will not be undergoing any procedures outlined in the recruitment plan in the near future.
4. Those with a body mass index of < 35.
5. Individuals may include siblings of those with FGIDs.
6. Parental/guardian permission (informed consent) and if appropriate, child assent.

Exclusion Criteria for Controls

1. History of skin allergies or a history of extreme sensitivity to cosmetics or lotions. Currently open wounds, abrasions, infected or inflamed abdominal skin.
2. Pregnant women.
3. Those with any condition, where fasting is not recommended by a physician.
4. Allergies to foods that may be included in the standardized meal that cannot be accommodated with an acceptable substitute meal.
5. Those with physical limitations, who are not able to maintain a relaxed reclined position for the study duration.
6. Those with major developmental delay or cognitive impairment, who are not able to report their symptoms/feelings in the questionnaires.
7. Those with GI motility disorders that are limited in the esophagus, and the gastric mapping is restricted to capture relevant data based on the investigator's discretion.
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Conditions & Interventions

Interventions:
DEVICE: Body surface gastric mapping device
Conditions:

Gastrointestinal Motility Disorders in Children, Functional Gastrointestinal Disorders, Gastroparesis, Dyspepsia and Other Specified Disorders of Function of Stomach
Keywords:
GI motility, gastroparesis, functional dyspepsia

More Information

Description:
The goal of this observational study is to learn about gastric myoelectric activity in children with GI symptoms. The main question it aims to answer is which patterns or signals are associated with GI symptoms as measured by a body surface gastric mapping (BSGM) device. Participants will have their stomach activity recorded for up to 4 hours using the BSGM device and log real-time symptoms. Researchers will compare the recordings of healthy children and children with GI symptoms to define abnormal GI patterns.

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