A Prospective, Multi-center, Single-arm Study of the Stomach, Intestinal and Pylorus Sparing (SIPS) Procedure

This study is ongoing, but not recruiting participants.

Sponsor:
Medtronic - MITG

Information provided by (Responsible Party):
Medtronic - MITG

ClinicalTrials.gov Identifier:
NCT02275208

First received: October 23, 2014
Last updated: January 12, 2016
Last verified: January 2016
History of Changes

Purpose

This study is a prospective, multi-center, single-arm study evaluating the SIPS procedure. Subjects who meet the eligibility criteria will be considered for study participation and will be followed through 12 months.

Condition	Intervention
Obesity	Procedure: SIPS the stomach, intestinal, pylorus, sparing procedure

Study Type: Observational
Study Design: Observational Model: Case-Only
Time Perspective: Prospective

Official Title: A Prospective, Multi-center, Single-arm Study of the Stomach, Intestinal and Pylorus Sparing (SIPS) Procedure

Further study details as provided by Medtronic - MITG:

Primary Outcome Measures:

- The primary endpoint is excess weight loss (EWL) at 12 months. [Time Frame: 12 months] [Designated as safety issue: No]

Secondary Outcome Measures:

- SIPS-related adverse events at all timepoints [Time Frame: 12 months] [Designated as safety issue: Yes]
- Resolution of comorbidities at 1, 6, and 12 months [Time Frame: 12 months] [Designated as safety issue: Yes]
- Quality of life (QOL) (SF-36 and gastroesophageal reflux disease - health related quality of life [GERD-HRQL]) at 6 and 12 months [Time Frame: 12 months] [Designated as safety issue: No]

Enrollment: 120
Study Start Date: November 2014
Estimated Study Completion Date: January 2017
Primary Completion Date: January 2016 (Final data collection date for primary outcome measure)

Intervention Details:

Procedure: SIPS the stomach, intestinal, pylorus, sparing procedure

Bariatric Procedure

Detailed Description:
SIPS is a single-anastomosis duodeno-intestinal switch procedure. Preliminary data from Sanchez-Pernaute et al. (Surg Obes Relat Dis 2013;9:731) indicates that this procedure is safe, quick to perform, and offers good results for treatment of both morbid obesity and its metabolic comorbidities. CovidienTM plans to further investigate this procedure and has proposed a prospective clinical study to obtain data on subject outcomes through 12 months following the SIPS procedure.

Eligibility

Ages Eligible for Study:	18 Years to 65 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

This is a prospective, multi-center, single-arm study. Patients who have elected to undergo bariatric surgery using the SIPS procedure (according to patient and investigator assessment and standard of care) will be evaluated for eligibility.

Criteria

Inclusion Criteria:

- The subject must be 18-65 years of age
- The subject must be willing and able to participate in the study procedures and to understand and sign the informed consent
- The subject is under consideration for surgery for obesity or metabolic disease and elects to undergo a primary SIPS procedure
- The subject has a BMI of 35-40 kg/m2 with at least 1 obesity-related comorbidity or a BMI of 40-60 kg/m2

Exclusion Criteria:

- Any female subject who is pregnant, or is actively breast-feeding
- Any subject who is considered to be part of a vulnerable population (e.g. prisoners or those with psychological concerns or those without sufficient mental capacity)
- The procedure is an emergency procedure
- The procedure is a revision/reoperation for the same indication
- The subject is unable or unwilling to comply with the study requirements or follow-up schedule
- The subject has conditions which, in the opinion of the investigator, will not be appropriate for the study (e.g. severe cardiovascular disease, history of gastrointestinal (GI) malignancy, history of upper GI surgery, open cholecystectomy, history of intestinal surgery, immunosuppression, or non-ambulatory)
- The subject has an estimated life expectancy of less than 6 months
- The subject has participated in an investigational drug or device research study within 30 days of enrollment

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02275208

Locations

United States, Colorado

Parker, Colorado, United States, 80134

United States, Florida

Florida Hospital Celebration Health
Celebration, Florida, United States, 34747

United States, New York

Mount Kisco, New York, United States, 10549
New York City, New York, United States, 10001

United States, North Carolina

Cary, North Carolina, United States, 27511
Durham, North Carolina, United States, 27701

United States, Utah

Salt Lake City, Utah, United States, 84101

Sponsors and Collaborators

Medtronic - MITG

More Information

No publications provided

Responsible Party:	Medtronic - MITG
ClinicalTrials.gov Identifier:	NCT02275208 History of Changes
Other Study ID Numbers:	COVSIPS0447
Study First Received:	October 23, 2014
Last Updated:	January 12, 2016
Health Authority:	United States: Institutional Review Board

ClinicalTrials.gov processed this record on February 04, 2016

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This study is ongoing, but not recruiting participants.

Sponsor:
Medtronic - MITG

Information provided by (Responsible Party):
Medtronic - MITG

ClinicalTrials.gov Identifier:
NCT02275208

First received: October 23, 2014
Last updated: January 12, 2016
Last verified: January 2016
History of Changes

Tracking Information

First Received Date ICMJE	October 23, 2014
Last Updated Date	January 12, 2016
Start Date ICMJE	November 2014
Primary Completion Date	January 2016 (final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE **(submitted: October 23, 2014)**	The primary endpoint is excess weight loss (EWL) at 12 months. [Time Frame: 12 months] [Designated as safety issue: No]
Original Primary Outcome Measures ICMJE	*Same as current*
Change History	Complete list of historical versions of study NCT02275208 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE **(submitted: October 23, 2014)**	• SIPS-related adverse events at all timepoints [Time Frame: 12 months] [Designated as safety issue: Yes] • Resolution of comorbidities at 1, 6, and 12 months [Time Frame: 12 months] [Designated as safety issue: Yes] • Quality of life (QOL) (SF-36 and gastroesophageal reflux disease - health related quality of life [GERD-HRQL]) at 6 and 12 months [Time Frame: 12 months] [Designated as safety issue: No]
Original Secondary Outcome Measures ICMJE	*Same as current*
Current Other Outcome Measures ICMJE	*Not Provided*
Original Other Outcome Measures ICMJE	*Not Provided*

Descriptive Information

Brief Title ICMJE	A Prospective, Multi-center, Single-arm Study of the Stomach, Intestinal and Pylorus Sparing (SIPS) Procedure
Official Title ICMJE	A Prospective, Multi-center, Single-arm Study of the Stomach, Intestinal and Pylorus Sparing (SIPS) Procedure

Brief Summary	This study is a prospective, multi-center, single-arm study evaluating the SIPS procedure. Subjects who meet the eligibility criteria will be considered for study participation and will be followed through 12 months.
Detailed Description	SIPS is a single-anastomosis duodeno-intestinal switch procedure. Preliminary data from Sanchez-Pernaute et al. (Surg Obes Relat Dis 2013;9:731) indicates that this procedure is safe, quick to perform, and offers good results for treatment of both morbid obesity and its metabolic comorbidities. CovidienTM plans to further investigate this procedure and has proposed a prospective clinical study to obtain data on subject outcomes through 12 months following the SIPS procedure.
Study Type ICMJE	Observational
Study Design ICMJE	Observational Model: Case-Only Time Perspective: Prospective
Target Follow-Up Duration	*Not Provided*
Biospecimen	*Not Provided*
Sampling Method	Non-Probability Sample
Study Population	This is a prospective, multi-center, single-arm study. Patients who have elected to undergo bariatric surgery using the SIPS procedure (according to patient and investigator assessment and standard of care) will be evaluated for eligibility.
Condition ICMJE	Obesity
Intervention ICMJE	Procedure: SIPS the stomach, intestinal, pylorus, sparing procedure Bariatric Procedure
Study Group/Cohort (s)	*Not Provided*
Publications *	*Not Provided*

*** Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.**

Recruitment Information

Recruitment Status ICMJE	Active, not recruiting
Enrollment ICMJE	120
Estimated Completion Date	January 2017
Primary Completion Date	January 2016 (final data collection date for primary outcome measure)
Eligibility Criteria ICMJE	Inclusion Criteria: • The subject must be 18-65 years of age • The subject must be willing and able to participate in the study procedures and to understand and sign the informed consent • The subject is under consideration for surgery for obesity or metabolic disease and elects to undergo a primary SIPS procedure • The subject has a BMI of 35-40 kg/m2 with at least 1 obesity-related comorbidity or a BMI of 40-60 kg/m2 Exclusion Criteria: • Any female subject who is pregnant, or is actively breast-feeding • Any subject who is considered to be part of a vulnerable population (e.g. prisoners or those with psychological concerns or those without sufficient mental capacity) • The procedure is an emergency procedure • The procedure is a revision/reoperation for the same indication • The subject is unable or unwilling to comply with the study requirements or follow-up schedule • The subject has conditions which, in the opinion of the investigator, will not be appropriate for the study (e.g. severe cardiovascular disease, history of gastrointestinal (GI) malignancy, history of upper GI surgery, open cholecystectomy, history of intestinal surgery, immunosuppression, or non-ambulatory)

	• The subject has an estimated life expectancy of less than 6 months • The subject has participated in an investigational drug or device research study within 30 days of enrollment
Gender	Both
Ages	18 Years to 65 Years
Accepts Healthy Volunteers	No
Contacts ICMJE	*Contact information is only displayed when the study is recruiting subjects*
Listed Location Countries ICMJE	United States
Removed Location Countries	

Administrative Information

NCT Number ICMJE	NCT02275208
Other Study ID Numbers ICMJE	COVSIPS0447
Has Data Monitoring Committee	No
Plan to Share Data	*Not Provided*
IPD Description	*Not Provided*
Responsible Party	Medtronic - MITG
Study Sponsor ICMJE	Medtronic - MITG
Collaborators ICMJE	*Not Provided*
Investigators ICMJE	*Not Provided*
Information Provided By	Medtronic - MITG
Verification Date	January 2016

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**