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Post-Gastric Bypass Hypoglycemia

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ClinicalTrials.gov Identifier: NCT01933490

Recruitment Status : Completed
First Posted : September 2, 2013
Last Update Posted : November 1, 2019

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Sponsor:
University of Minnesota

Information provided by (Responsible Party):
University of Minnesota

Study Details | Tabular View | No Results Posted | Disclaimer

How to Read a Study Record

Study Description

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Brief Summary:

Post-gastric bypass hyperinsulinemic hypoglycemia is a recently described disorder occurring in some patients after gastric bypass surgery for obesity. The pathogenesis is incompletely understood but involves a robust insulin response to ingested carbohydrate. The resultant hyperinsulinemia sometimes produces hypoglycemia with neuroglycopenia,

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confusion and even loss of consciousness. Various treatments have been recommended including low carbohydrate diets, coingestion of the medication acarbose with carbohydrate containing meals, partial pancreatectomy and even total pancreatectomy. None is completely satisfactory. We propose to test two new potential treatments. Using a design with random assignment of three conditions we plan to compare, in 10 patients with post-gastric bypass hyperinsulinemic hypoglycemia, a high carbohydrate test meal (control condition), a high carbohydrate test meal after pre-treatment with rapid acting aspart insulin (insulin condition), and a high fructose, low glucose test meal with carbohydrate and caloric content similar to the control meal (fructose condition).

Condition or disease	Intervention/treatment	Phase
Hyperinsulinemic Hypoglycemia	Other: high carbohydrate test meal Other: high carbohydrate test meal after pre-treatment with rapid acting aspart insulin Other: high fructose , low glucose test meal with carbohydrate and caloric content similar to the control meal	Not Applicable

Detailed Description:

Post-gastric bypass hyperinsulinemic hypoglycemia is a recently described disorder occurring in some patients after gastric bypass surgery for obesity. The pathogenesis is incompletely understood but involves a robust insulin response to ingested carbohydrate. The resultant hyperinsulinemia sometimes produces hypoglycemia with neuroglycopenia, confusion and even loss of consciousness. Various treatments have been recommended including low carbohydrate diets, coingestion of the medication acarbose with carbohydrate containing meals, partial pancreatectomy and even total pancreatectomy. None is completely satisfactory. We propose to test two new potential treatments. Using a design with random assignment of three conditions we plan to compare, in 10 patients with post-gastric bypass hyperinsulinemic hypoglycemia, a high carbohydrate test meal (control condition), a high carbohydrate test meal after pre-treatment with rapid acting aspart insulin (insulin condition), and a high fructose, low glucose test meal with carbohydrate and caloric content similar to the control meal (fructose condition). The hypothesis to be tested are 1) pretreatment with aspart insulin will prevent, or at least reduce, the occurrence of hypoglycemia and 2) substitution of fructose for glucose in the test meal will prevent, or at least reduce, the occurrence of hypoglycemia. Plasma glucose and serum insulin will be sampled before and for four hours after the three test conditions. The primary study endpoint will be the occurrence or not of plasma glucose < 60 mg/dL after the test meals. The control meal will be compared to the insulin pre-treated test meal and, in a separate comparison, to the fructose test meal. Secondary endpoints will be comparisons between the control and active treatments in peak postprandial serum insulin, peak postprandial plasma glucose, nadir postprandial plasma glucose, and the 4-hr longitudinal course of plasma glucose measurements.

Study Design

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Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	10 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment

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Masking:	None (Open Label)
Primary Purpose:	Health Services Research
Official Title:	Prevention of Hypoglycemia in Patients With Post-Gastric Bypass Hyperinsulinemic Hypoglycemia
Study Start Date :	August 2013
Actual Primary Completion Date :	August 2014
Actual Study Completion Date :	August 2014

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: Congenital hyperinsulinism

MedlinePlus related topics: Hypoglycemia

Genetic and Rare Diseases Information Center resources: Congenital Hyperinsulinism

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
a high carbohydrate test meal (control condition) a high carbohydrate test meal (control condition)	Other: high carbohydrate test meal Other: high carbohydrate test meal after pre-treatment with rapid acting aspart insulin Other: high fructose , low glucose test meal with carbohydrate and caloric content similar to the control meal
Active Comparator: high carbohydrate test meal after pre-treatment a high carbohydrate test meal after pre-treatment with rapid acting aspart insulin (insulin condition)	Other: high carbohydrate test meal Other: high carbohydrate test meal after pre-treatment with rapid acting aspart insulin Other: high fructose , low glucose test meal with carbohydrate and caloric content similar to the control meal
Active Comparator: high fructose low glucose test meal high fructose , low glucose test meal with carbohydrate and caloric content similar to the control meal (fructose condition)	Other: high carbohydrate test meal Other: high carbohydrate test meal after pre-treatment with rapid acting aspart insulin Other: high fructose , low glucose test meal with carbohydrate and caloric content similar to the control meal

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Outcome Measures

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Primary Outcome Measures :

1. The primary study endpoint will be occurrence or not of plasma glucose < 60 mg/dL during the 4 hours after the test meal (binary endpoint). [Time Frame: 4 hours after meal]

   The primary study endpoint will be occurrence or not of plasma glucose < 60 mg/dL during the 4 hours after the test meal (binary endpoint).

Eligibility Criteria

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Information from the National Library of Medicine

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, Learn About Clinical Studies.

Ages Eligible for Study:	21 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Participants must be at least 21 years of age
- History of postprandial hypoglycemia with neuroglycopenia occurring one year or more after gastric bypass surgery
- History of spontaneous correction of hypoglycemia
- Normal fasting plasma glucose and serum insulin after a carbohydrate containing mixed meal, demonstration of serum insulin > 50u/UL and plasma glucose < 50mg/dL

Exclusion Criteria:

- Under 21 years of age

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Contacts and Locations

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Information from the National Library of Medicine

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number):
NCT01933490

Locations

United States, Minnesota

University of Minnesota
Minneapolis, Minnesota, United States, 55455

Sponsors and Collaborators

University of Minnesota

Investigators

Principal Investigator: John Bantle, MD University of Minnesota

More Information

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Bantle AE, Wang Q, Bantle JP. Post-Gastric Bypass Hyperinsulinemic Hypoglycemia: Fructose is a Carbohydrate Which Can Be Safely Consumed. J Clin Endocrinol Metab. 2015 Aug;100(8):3097-102. doi: 10.1210/jc.2015-1283. Epub 2015 Jun 2.

Responsible Party:	University of Minnesota
ClinicalTrials.gov Identifier:	NCT01933490 History of Changes
Other Study ID Numbers:	1306M37181
First Posted:	September 2, 2013 Key Record Dates
Last Update Posted:	November 1, 2019
Last Verified:	October 2019

Keywords provided by University of Minnesota:
hyperinsulinemic hypoglycemia

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Additional relevant MeSH terms:

- Congenital Hyperinsulinism
- Nesidioblastosis
- Hypoglycemia
- Glucose Metabolism Disorders
- Metabolic Diseases
- Pancreatic Diseases
- Digestive System Diseases
- Infant, Newborn, Diseases
- Hyperinsulinism
- Insulin Aspart
- Hypoglycemic Agents
- Physiological Effects of Drugs

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