

Metabolism after surgery

Submission date 30/01/2017	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/02/2017	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/01/2020	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

It is widely acknowledged that surgery on the gastrointestinal tract (gut), particularly the stomach and oesophagus (gullet), changes the way the body senses and processes food. While undergoing these procedures can prove beneficial, in many cases patients suffer problematic symptoms after surgery. These particularly include the “dumping syndrome”, where a person may feel flushed, faint or even pass out after a meal. Some believe that these symptoms are caused by an overactive response of certain cells in the lining of the gut to food. These cells produce chemical signals (hormones) which would normally tell the body how much food has been eaten, and how to deal with it. When too much of one of these hormones is produced, the body can react badly and make someone unwell. This study aims to understand what hormones are altered by surgery, why this happens and how the impact of this problem in people can be reduced in people who have had surgery on their gastrointestinal tract.

Who can participate?

Healthy volunteers, and adults who have undergone, or are due to undergo, surgery to remove all or part of the stomach or oesophagus.

What does the study involve?

All participants are asked to complete questionnaires and attend for a sugar drink test, during which their blood sugar levels are monitored by taking and testing blood samples. Smaller groups of participants who have had surgery are invited to participate in more detailed studies, including identification and treatment of altered levels of bacteria in the small intestine, continuous glucose monitoring (continuously measuring blood sugar levels using a special device that is worn on the body) in the community and collection of tissue biopsies (samples) during surgery or subsequent endoscopy.

What are the possible benefits and risks of taking part?

After surgery, patients will benefit from having the opportunity to explore their altered eating habits and associated symptoms in a controlled environment. This is a very poorly understood field, and it is hoped that by defining the problems experienced by this group researchers can start to explore novel treatment strategies in the future. There are rare risks associated with taking part, during the glucose tolerance test there is a risk of feeling unwell and transient low blood sugar levels, endoscopy carries risks of bleeding or damage to the bowel but these are both very unlikely.

Where is this study run from?
Addenbrooke's Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2016 to October 2021

Who is funding the study:
1. National Institute of Health Research (UK)
2. Wellcome Trust (UK)
3. Medical Research Council (UK)

Who is the main contact?
Mr Geoffrey Roberts
gpr25@cam.ac.uk

Contact information

Type(s)
Public

Contact name
Mr Geoffrey Roberts

ORCID ID
<http://orcid.org/0000-0001-9554-8404>

Contact details
Addenbrooke's Hospital
Box 289
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 1223 767176
gpr25@cam.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02836353

Secondary identifying numbers
33469

Study information

Scientific Title

The metabolic consequences of gastrointestinal surgery

Study objectives

The aim of this study is to evaluate the the metabolic consequences of surgery, define new approaches to the diagnosis and management of dumping syndrome, and improve knowledge of human gastrointestinal and metabolic physiology.

Ethics approval required

Old ethics approval format

Ethics approval(s)

East of England – Cambridge South REC, 28/11/2016, ref: 16/EE/0338

Study design

Non-randomised; Both; Design type: Treatment, Drug, Cohort study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Gastrointestinal surgery

Interventions

A cohort of patients who have undergone surgery on the stomach or oesophagus will be recruited to undergo cognitive (questionnaire) and metabolic (oral glucose tolerance test) assessment. If recruited within two years of surgery, the participant will complete questionnaires at 3, 6, 12 and 24 months post-surgery. If greater than two years post-surgery participants will complete a single assessment.

A subset of up to 15 participants identified with small intestinal bacterial overgrowth on hydrogen / methane breath testing will be treated with Rifaximin 400mg TDS for 7 days and then have a repeat oral glucose tolerance test. This is an open label study to assess the effect of treatment of bacterial overgrowth (common in this group) on secretion of gut derived hormones and metabolic indices / glucose metabolism.

A subset of up to 15 participants identified with severe metabolic complications of surgery and deranged gut hormone secretion will receive a single dose of 50 micrograms of subcutaneous octreotide immediately prior to a repeat glucose tolerance test to assess the effects of gut hormone suppression on metabolic indices and glucose metabolism.

Intervention Type

Other

Primary outcome measure

Plasma glucose is measured by the hexokinase method at 15, 30, 45, 60, 90, 120, 150 and 180 minutes post 50g glucose tolerance test.

Secondary outcome measures

1. Plasma Insulin is measured by sandwich ELISA at 15, 30, 45, 60, 90, 120, 150 and 180 minutes post 50g glucose tolerance test
2. Plasma total GLP-1 is measured by MSD sandwich ELISA at 15, 30, 45, 60, 90, 120, 150 and 180 minutes post 50g glucose tolerance test
3. Hunger and fullness are measured by visual analogue scales (range 0-100) at 15, 30, 45, 60, 90, 120, 150 and 180 minutes post 50g glucose tolerance test

Overall study start date

07/07/2016

Completion date

01/10/2021

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

1. Aged 18 years and over
2. Capacity to give voluntary informed consent
3. Undergone, or have planned within the next 12 months, surgery including removal of all or part of the stomach or oesophagus; or be a carrier of a genetic mutation conferring a high risk of requiring a future prophylactic gastrectomy

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 200; UK Sample Size: 200

Key exclusion criteria

All participants:

1. Aged under 18 years
2. Recent history of untreated anaemia
3. Lack capacity to read and retain information about the study
4. Communication issues which prevent accurate understanding of the study rationale and requirements

Post-operative participants:

1. Recurrent gastric or oesophageal cancer

Participants for endoscopy:

1. Contraindication to upper gastrointestinal endoscopy
2. Taking medication that would pose a significant risk of haemorrhage after biopsy (e.g. Clopidogrel, Warfarin, Dipyridamole, novel oral anticoagulants, therapeutic dose heparin)
3. Significant medical comorbidity that may be adversely affected by endoscopy or sedation (e.g. unstable ischaemic heart disease, significant respiratory impairment)

Participants for physiological challenge with antibiotics or Somatostatin analogue:

1. Known allergy to the proposed agent
2. Received a course of antibiotics in the preceding two months
3. Suffer from a known illness that may be exacerbated by the proposed agent
4. Be on medication which interacts with the proposed agent

Date of first enrolment

16/01/2017

Date of final enrolment

01/10/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Addenbrooke's Hospital

Hills Road

Cambridge

United Kingdom

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust

Sponsor details

Box 277
Addenbrookes Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ
+44 1223 217418
R&denquiries@addenbrookes.nhs.uk

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Wellcome Trust

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal: interim findings 2018, final findings 2022.

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication - it is anticipated that full datasets will be made available through the University of Cambridge data repository.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3	11/11/2016	03/02/2017	No	Yes
Participant information sheet	version V2	19/09/2016	03/02/2017	No	Yes
HRA research summary			28/06/2023	No	No