

# Non-invasive detection of electrical signals from the stomach after major pancreas surgery

<b>Submission date</b> 14/09/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/04/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/05/2024	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Major pancreas resection surgery (pancreaticoduodenectomy), which is performed in patients with pancreas and duodenal cancer, is complex and has a high rate of complication. A part of this operation involves disconnecting the stomach from its normal position and reconnecting it to the small intestine. This often results in 'delayed gastric emptying', where the stomach moves abnormally and is not able to receive and digest food in the normal way. Patients who suffer from this complication are unable to eat or drink for a few weeks after their surgeries, causing prolonged hospital stays and significant patient suffering. The exact mechanism for this complication is not well understood, making it difficult to predict which patients will have delayed gastric emptying after surgery. Different techniques for connecting the stomach to the small intestine have been developed but it is unclear which of these has the greatest potential to prevent this complication. The contracting action of the stomach is coordinated by electrical signals, much like that in the heart. Recently, a new technology termed 'Body Surface Gastric Mapping' has been developed to measure these electrical signals non-invasively from the skin, similar to the manner in which an ECG analyses the electrical impulses from the heart. Using this technology, specific patterns have been shown in patients with various disorders of the stomach. This study aims to use this new technology to analyse the pattern of electrical signals from the stomach in patients who have had major pancreas surgery and who may go on to develop delayed gastric emptying. This will help to predict which patients are likely to have this complication and develop better techniques for preventing and treating it in the future.

### Who can participate?

Adult patients aged over 18 years old undergoing pancreaticoduodenectomy for malignant or benign disease of the pancreas, distal bile duct or duodenum

### What does the study involve?

Body surface gastric mapping will be used to analyse gastric electrical activity in patients before and at multiple time points after pancreaticoduodenectomy. These data will be correlated with patient-reported symptoms of delayed gastric emptying.

What are the possible benefits and risks of participating?

There are no benefits to the participants of the study. There is a theoretical risk of skin allergy to the adhesive used on the electrode array, but this has not occurred in other studies.

Where is the study run from?

University Hospital Coventry And Warwickshire (UK)

When is the study starting and how long is it expected to run for?

May 2021 to July 2025

Who is funding the study?

The study is funded by the Newcastle Hospitals Charity Fund (UK)

Who is the main contact?

Dr Keno Mentor, keno.mentor@nhs.net

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Keno Mentor

### ORCID ID

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

305302

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

10062, IRAS 305302

## Study information

**Scientific Title**

Body surface gastric mapping to determine gastric motility patterns associated with delayed gastric emptying after pancreaticoduodenectomy

**Acronym**

GEMAP

**Study objectives**

Major pancreatic surgery results in electrical aberrations in the stomach which cause delayed gastric emptying

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 08/06/2022, North West - Greater Manchester Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 1048 007; gmcentral.rec@hra.nhs.uk), ref: 22/NW/0148

**Study design**

Multi-centre prospective cohort study

**Primary study design**

Observational

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Delayed gastric emptying in patients who undergo pancreaticoduodenectomy

**Interventions**

Participants will undergo Body Surface Gastric Mapping (BSGM) at multiple points in their patient journey. BSGM involves applying a multi-electrode array to the surface of the abdominal wall, which detects and analyses electrical signals from the stomach. The detector will be left in place for 4 hours and cause the patient no pain and minimal discomfort. During this procedure, the patient will also log their abdominal symptoms (e.g. nausea) using a smartphone application designed specifically for this study. In so doing, the patient's symptoms will be correlated with the BSGM analysis.

This procedure will be carried out at multiple time points:

- before surgery
- on the fifth day following surgery
- once a week until discharge
- 3 months after discharge
- 6 months following discharge

\*\*Please note that the above schedule has been changed in subsequent amendments to:

- before surgery
- on the 4th day following surgery

- on the day of discharge
- 6 months following discharge

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Gastric Alimetry

**Primary outcome(s)**

Wave spectral (frequency and amplitude), spatial (wave directional vector) and stability (rhythm index) parameters measured using gastric Alimetry at the following timepoints: pre-operatively, day 4 postoperatively, at discharge and 6 months postoperatively.

**Key secondary outcome(s)**

1. Quality of life measured using the Patient Assessment of upper GastroIntestinal disorders- Quality of Life (PAGI QoL) questionnaire at 6 months
2. Patient satisfaction measured using a bespoke questionnaire designed by the researchers at 6 months

**Completion date**

31/07/2025

## Eligibility

**Key inclusion criteria**

Patients undergoing pancreaticoduodenectomy for malignant or benign disease of the pancreas, distal bile duct or duodenum

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Under 18 years of age
2. Previous gastric surgery

3. Post-operative complications requiring surgical intervention
4. Major wound sepsis or rash
5. History of skin allergies or extreme sensitivity to cosmetics or lotions
6. Pregnant women
7. Vulnerable groups e.g. cognitive impairment or inability to give consent

**Date of first enrolment**

01/12/2022

**Date of final enrolment**

31/12/2024

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**The Newcastle upon Tyne Hospitals NHS Foundation Trust**

Freeman Hospital

Freeman Road

High Heaton

Newcastle upon Tyne

United Kingdom

NE7 7DN

**Study participating centre**

**Churchill Hospital**

Churchill Hospital

Old Road

Headington

Oxford

United Kingdom

OX3 7LE

## Sponsor information

**Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR

<https://ror.org/05p40t847>

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

Newcastle University

### **Alternative Name(s)**

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Universities (academic only)

### **Location**

United Kingdom

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from Dr Keno Mentor (keno.mentor@nhs.net). Patient consent includes granting permission for the dissemination of non-identifiable data.

### **IPD sharing plan summary**

Available on request