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

Submission date
14/09/2023

Recruitment status
No longer recruiting

Registration date
23/04/2024

Overall study status
Completed

Last Edited
08/05/2024

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
305302

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gastric Alimetry

Primary outcome measure
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.

Secondary outcome measures
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

Overall study start date
01/05/2021

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

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
England

United Kingdom

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

Sponsor details
Newcastle Joint Research Office
Level 1, Regent Point
Newcastle upon Tyne
England
United Kingdom
NE3 3HD
+44 (0)191 233 6161
nuth.nuthsponsorship@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

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

Publication and dissemination plan
Non-identifiable and anonymised data and findings will be published in peer-reviewed journals and presented at national and international conferences.

Intention to publish date
31/07/2025

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