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Effects of chewing gum on gastric distention in patients undergoing laparoscopic cholecystectomy

Submission date	Recruitment status	[_] Prospectively registered
30/09/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/10/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/10/2024	Digestive System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims at consenting adult (≥ 18 years old) patients undergoing laparoscopic cholecystectomy due to gallstones or gallbladder polyps. It will involve chewing gum 30 minutes before the procedure to help decrease gastric distention and promote safer surgery through better visualization of vital structures.

Who can participate?
Adult patients (≥ 18 years old) undergoing laparoscopic cholecystectomy due to gallstones or gallbladder polyps

What does the study involve?
Participants will chew gum 30 minutes before their procedure to help decrease gastric distention. The study will compare the outcomes with standard procedures to assess the effects of this intervention.

What are the possible benefits and risks of participating?
While patients may not directly benefit, the study may provide valuable information on the efficacy of chewing gum in decreasing gastric distention before laparoscopic cholecystectomy. This could potentially reduce the use of nasogastric tubes and decrease hospital stay lengths.
Risks include common complications of Laparoscopic Cholecystectomy such as:
1. Conversion to open cholecystectomy (2 - 7%)
2. Biliary duct injury (0.4 - 0.6%) or biliary fistulas (0.5%)
3. Vascular injury (0.3%) or postoperative bleeding (0.5%)
4. Intestinal injury (0.09%)
5. Infections (4%)
6. Other complications related to anesthesia and patient comorbidities.

Where is the study run from?
The study will be run from Bulacan Medical Center, City of Malolos, Bulacan.

When is the study starting and how long is it expected to run for?
November 2022 to May 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr. Sofia Isabel Ribeiro - Yadav, sisabelribeiro94@gmail.com.

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effects of chewing gum on gastric distention in patients undergoing laparoscopic cholecystectomy: a single centre study

Study objectives

Chewing gum has been proven time and again for use in promoting gastrointestinal motility post-operatively, especially in patients who undergo colorectal surgery. This study aims to use chewing gum preoperatively to decrease gastric distention thereby promoting better visualization of vital structures during laparoscopic cholecystectomy.

The hypothesis is that chewing gum will aid in decreasing gastric distention.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/05/2024, Research Ethics Committee (La Consolacion University Philippines, Bulihan, City of Malolos, 3000, Philippines; +63 44 931 8600; research.ethics.comm@email.lcup.edu.ph), ref: 1062/202405-YadavS00

Study design
Single-blind randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
The effect of chewing gum on gastric distention in patients undergoing laparoscopic cholecystectomy

Interventions
All consenting patients underwent Laparoscopic Cholecystectomy only from November 1, 2022, to May 31, 2024.

Participants will undergo random sampling and be assigned to group NG (“no gum”) and group CG (“chewing gum”).

Pre-operative Chewing Gum is the intervention.

A locally branded xylitol-based mint-flavoured chewing gum was provided to the study participants randomly assigned to the "Chewing Gum" (CG) group by junior general surgery resident doctors to chew for 30 minutes before their transfer to the operating room.

The intervention took place in the surgery ward.

The intervention was only delivered once, 30 minutes before the patient's scheduled operation.

No tailoring was done.

There were no modifications done to the intervention during the study.

Adherence to the trial participant's chewing of gum was assessed using a checklist accomplished by junior general surgery resident doctors wherein the participant was asked to start chewing their gum under direct observation of the junior general surgery resident and also asked to dispose of their gum after 30 minutes in front of the same observer.

Intervention Type
Procedure/Surgery

Primary outcome measure
The visual presence of gastric distention during the performance of limited diagnostic laparoscopy measured using nasogastric tubes at the start of the procedure.
If (+) gastric distention impedes visualization and identification of vital structures, then a nasogastric tube will be used before proceeding with the cholecystectomy.
If (-) gastric distention, the no nasogastric tube will be used and the senior general surgery resident doctor will proceed with the cholecystectomy.

Secondary outcome measures
1. Duration of hospitalization measured using the number of hospital days per patient recorded in study notes at one timepoint
2. Decrease in operative time measured using the mean of the number of minutes per procedure recorded in study notes at one timepoint
3. If this intervention provides additional discomfort to the patient measured using the Wong-Baker Faces Pain Scale 8 hours post-operatively
4. If the intervention adds additional costs to the patient measured using descriptive methods as chewing gum in the Philippines is Php 1.00 (which is approx. GBP 0.01) at one timepoint
5. If the intervention helps in decreasing intraoperative injuries measured using descriptive methods at one timepoint

Overall study start date
01/11/2022

Completion date
31/05/2024

Eligibility

Key inclusion criteria
1. Aged 18 years and older
2. Undergo elective laparoscopic cholecystectomy
3. Indication of cholelithiasis or gallbladder polyp
4. Agree to participate in the study
5. Operations performed by general surgery residents of the same level of training

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
176

Total final enrolment
190

Key exclusion criteria
1. Patients aged less than 18 years old
2. Undergo laparoscopic cholecystectomy with other pathologies
3. Performed by general surgery consultants/attendings
4. Those who do not undergo laparoscopic cholecystectomy
5. Oesophageal intubation
6. Patients who do not agree to participate
7. Patients who have undergone previous gastric surgery
8. Patients at risk of aspiration

Date of first enrolment
01/11/2022

Date of final enrolment
23/05/2024

Locations

Countries of recruitment
Philippines

Study participating centre
Bulacan Medical Center
99 Potenciano St., Department of Surgery, Bulacan Medical Center, Brgy. Mojon
City of Malolos
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Sponsor information

Organisation
Bulacan Medical Center

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Sponsor type
Hospital/treatment centre

Website
https://bulacan.gov.ph/health/bulacan-medical-center/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Bulacan Medical Center, Department of Surgery

Results and Publications

Publication and dissemination plan
Planned publication to SAGES Surgical Endoscopy.

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
Data requests can be submitted starting 9 months after article publication and the data will be made accessible for up to 24 months. Extensions will be considered on a case-to-case basis.

Access to trial IPD can be requested by qualified researchers engaging in independent scientific research and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA). For more information or to submit a request, please contact sisabelribeiro94@gmail.com

IPD sharing plan summary

Available on request