

Impact of preoperative oral honey solution on postoperative recovery

Submission date 12/12/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/12/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/12/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Preoperative fasting has a long and evolving history in medical practice, dating back to the early days of modern anesthesia. Research in the 1980s and 1990s demonstrated that clear fluids are cleared from the stomach within 2 to 3 hours, which was the end of the era when the recommendation was to withhold food and liquids for 7-8 hours before surgery. Prolonged fasting impacts both the stress response and metabolic effects on the human body. Shortened fasting time and provision of a preoperative carbohydrate load have been associated with multiple benefits and enhanced recovery after surgery. Honey is a natural carbohydrate-rich substance with a complex composition that may offer additional benefits beyond those of commercially available carbohydrate solutions. Honey may have anti-inflammatory, antioxidant, and antimicrobial properties. Incorporating honey into preoperative carbohydrate loading could further improve postoperative outcomes. This study aims to contribute to a growing body of literature supporting more individualized and beneficial preoperative nutritional strategies.

Who can participate?

Patients aged 18 years and over who are scheduled for elective laparoscopic cholecystectomy

What does the study involve?

After admission patients will be randomly selected to receive either an in-house prepared oral honey solution or a commercially available standardized carbohydrate solution. Both groups will receive 800 ml of their assigned solution on the evening before surgery and an additional 200 ml 2 hours before anesthesia induction. No solid food will be permitted for both groups after midnight. Blood samples will be taken at predefined intervals before and after surgery.

What are the possible benefits and risks of participating?

Participants could benefit from improved postoperative outcomes and shortened recovery time.

Where is the study run from?

Clinical Hospital Center Rijeka (Croatia)

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

May 2021 to August 2022

Who is funding the study?
Clinical Hospital Center Rijeka (Croatia)

Who is the main contact?
Ivan Vuksan, ivan.vuksan@uniri.hr

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

12345

Study information

Scientific Title

Effect of preoperative honey consumption on postoperative stomach motility and body stress response

Study objectives

Preoperative intake of an in-house prepared honey solution will result in same postoperative gastric motility and stress response compared to a commercially available carbohydrate solution in patients undergoing elective laparoscopic cholecystectomy.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 13/05/2021, Clinical Hospital Center Rijeka Ethics Committee (Kresimirova 42, Rijeka, 51000, Croatia; +385 (0)51658808; ravnateljstvo@kbc-rijeka.hr), ref: 2170-29-02/1-21-2

Study design

Single-center interventional single-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

Postoperative gastric motility and stress response in patients undergoing elective laparoscopic cholecystectomy

Interventions

Using a simple method of randomisation, patients were randomly assigned in a 1:1 ratio in the order of their admission into the hospital to receive either an in-house prepared oral honey solution (locally sourced honey diluted in warm sterile water to a carbohydrate-rich clear fluid) or a commercially available standardized carbohydrate solution (Nutricia preOp®; Nutricia Advanced Medical Nutrition, Zoetermeer, The Netherlands). Both groups received 800 ml of their assigned solution orally on the evening before surgery and an additional 200 ml 2 hours prior to anesthesia induction.

Intervention Type

Supplement

Primary outcome measure

1. Stress response, serum cortisol concentrations measured twice daily (08:00 and 16:00) on the day before surgery, on the day of surgery, and on the first postoperative day. Blood samples were collected into EDTA tubes and analyzed using validated commercial immunoassay kits.
2. Gastric motility was assessed indirectly through a paracetamol absorption test performed at baseline and 15, 30, 60, 120, and 180 minutes after ingestion using the ACET2 assay on a COBAS INTEGRA analyzer.

Secondary outcome measures

Stress response measured using interleukin-6 (IL-6) levels at four timepoints: the day before surgery at 08:00, the morning of surgery at 08:00, six hours postoperatively, and on the first postoperative day at 16:00. The blood samples were collected into EDTA tubes and analyzed using validated commercial immunoassay kits.

Overall study start date

03/05/2021

Completion date

16/08/2022

Eligibility

Key inclusion criteria

1. Adult patients (≥ 18 years)
2. American Society of Anesthesiologists (ASA) physical status I–II
3. Scheduled for elective laparoscopic cholecystectomy

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20

Total final enrolment

20

Key exclusion criteria

1. History of neurosurgical procedures or head injuries
2. Prior hepatobiliary or gastrointestinal surgeries
3. Chronic renal insufficiency (creatinine clearance < 50 mL/min)
4. Hepatobiliary disease within the last 6 months (e.g., cholecystitis, pancreatitis)
5. Acute hepatobiliary disease defined by more than threefold elevation of transaminases, twice the normal prothrombin time, or total bilirubin elevated threefold above the normal range
6. Known drug allergies or adverse reactions related to the study medications
7. Insulin-dependent diabetes mellitus
8. Severe chronic obstructive pulmonary disease
9. Significant cardiovascular disease
10. Myocardial infarction within 3 weeks
11. Preoperative left ventricular ejection fraction $< 40\%$
12. Advanced malignant disease

- 13. ASA status >3
- 14. Emergency surgery
- 15. Intraoperative identification of gallbladder inflammation
- 16. Conversion to open cholecystectomy
- 17. Advanced malignant disease discovered during the procedure
- 18. Intraoperative complications (e.g., significant bleeding, organ injury, or need for extended surgical resection)

Date of first enrolment

15/02/2022

Date of final enrolment

27/06/2022

Locations

Countries of recruitment

Croatia

Study participating centre

Clinical Hospital Center Rijeka

Kresimirova 42

Rijeka

Croatia

51000

Sponsor information

Organisation

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Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://kbc-rijeka.hr>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Clinical Hospital Center Rijeka

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

24/02/2025

Individual participant data (IPD) sharing plan

Data will be available on request from principal investigator Janja Tarcukovic (janja.kuharic@uniri.hr).

IPD sharing plan summary

Available on request