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Impact of preoperative oral honey solution on postoperative recovery

Submission date 12/12/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 16/12/2024	**Overall study status** Completed	
Last Edited 16/12/2024	**Condition category** Surgery	

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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
Clinical Hospital Center Rijeka

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Clinical Hospital Center Rijeka

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes