ISRCTN35969703 https://doi.org/10.1186/ISRCTN35969703

Environmental impact calculator for minimally invasive surgical gallbladder removal

Submission date
13/03/2026

Recruitment status
Recruiting

Registration date
16/03/2026

Overall study status
Ongoing

Last Edited
16/03/2026

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
One of the greatest threats to public health in the 21st century is anthropogenic climate change. Healthcare services worldwide account for 4.9% of global carbon dioxide emissions, which is higher than aviation or shipping. Operating rooms are among the most resource-intensive areas of the hospital. The aim of this study is to implement a validated, easily accessible, and user-friendly calculator tool to analyse the annual carbon footprint for minimally invasive surgeries, irrespective of hospital volume, hospital income, or surgical specialty. This assessment could be used for, but not limited to, (inter)national benchmarking, research homogeneity, progress on sustainable changes, and hospital-specific, tailor-made advice on potential improvements. This project starts with a study on minimally invasive surgical gallbladder removal, one of the most performed surgeries worldwide.

Who can participate?
An international expert steering committee will be convened, consisting of recognized experts in hepatopancreatobiliary surgery, general surgery, environmental sciences, and healthcare sustainability. Expert participants will be recruited through professional networks within the European Association for Endoscopic Surgery (EAES) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) to fill in the calculator tool and leave their impressions.
No patients will be recruited for this study.

What does the study involve?
The ECOMIS project follows a multiphase, stepped design. The present study will focus on minimally invasive cholecystectomies. The calculator variables will be selected based on a targeted literature review regarding factors influencing carbon dioxide equivalents (CO2-eq), with life cycle assessment (LCA) considered the most reliable method in determining environmental impact. This will be carried out via a three-step process. Step 1: The calculator will be developed based on an extensive literature review. Step 2: a Delphi study within the ECOMIS expert steering committee with the goal of refining and identifying potential improvements. Step 3: External validation of the calculator.

What are the possible benefits and risks of participating?
A potential benefit of participation is the individualized insight into the environmental impact of minimally invasive gallbladder removal. This could help with sustainable decision-making.
There is no potential risk for participating in this study. No patients will be included in this study. The data of the experts participating in this study will be anonymized.

Where is the study run from?
The study is coordinated by the ECOMIS team, based in the Netherlands, Poland, Spain, Malta, and the United Kingdom.

When is the study starting and how long is it expected to run for?
April 2026 to July 2027

Who is funding the study?
European Association of Endoscopic Surgery (Netherlands)

Who is the main contact?
Dr Hidde Overtoom, h.c.g.overtoom@amsterdamumc.nl

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Hidde Overtoom

Contact details
De Boelelaan 1117
Amsterdam
Netherlands
1081HV
+31 (0)630428132
h.c.g.overtoom@amsterdamumc.nl

Additional identifiers

Study information

Scientific Title
Development of the environmental impact calculator for minimally invasive cholecystectomies

Acronym
ECOMIS

Study objectives
The aim of this study is to develop and implement a validated, easily accessible, and user-friendly calculator to quantitatively analyze the CO2-eq of minimally invasive surgery, irrespective of country, hospital volume, and hospital income. This quantitative assessment could be used for, but not limited to, problem comprehension, (inter)national benchmarking, research

homogeneity, progress assessment, and hospital-specific tailor-made advice on potential improvements.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/01/2026, Bioethics Committee of the University of Warmia and Mazury (Warszawska 30, Olsztyn, 10-082, Poland; +48 (0)89 524 53 04; beata.gwiazda@uwm.edu.pl), ref: 06/2026

Primary study design
Observational

Secondary study design
Multiphase stepped design including a systematic literature search, Delphi consensus study and external validation

Study type(s)

Health condition(s) or problem(s) studied
Minimally invasive cholecystectomies

Interventions
This study will follow a multiphase, stepped approach to develop a sustainability calculator for minimally invasive cholecystectomy (MIC). The calculator is part of the Environmental Impact Calculator for Minimally Invasive Surgery (ECOMIS) project. The study protocol was developed in accordance with i) the PRISMA-P guidelines for literature reviews, ii) ACCORD guidelines for consensus studies, and iii) SPIRIT-Outcomes guidelines for reporting study outcomes. The present study consists of three main phases: calculator development, expert Delphi consensus survey, and external validation.

Phase I: Literature review and variable selection
A systematic literature review will be conducted to identify factors contributing to the CO2-eq of minimally invasive cholecystectomy. The review will follow the Preferred Reporting Items for Systematic Review and Meta-Analyses Protocols (PRISMA-P) guidelines. The primary search will be performed in the Healthcare Life Cycle Assessment (HealthcareLCA) database, a comprehensive and globally recognized repository for LCA studies in healthcare.

A complementary literature review will be performed in Embase, PubMed and Google Scholar to identify potentially relevant studies not indexed in the HealthcareLCA database. The full search strategy will be provided as supplementary material. Studies published from database inception up to 01 April 2026 will be eligible for inclusion. Inclusion criteria comprise original studies performing an LCA of healthcare-related interventions, procedures, logistics, or equipment, reporting environmental impact as kilograms of carbon dioxide equivalents (CO2-eq). Environmental impact is defined as CO2-eq, as this is the most widely accepted and standardized metric for healthcare-related environmental assessments. Studies focusing on cholecystectomy-related procedures or equipment will be prioritized. Exclusion criteria include LCAs of non-medical interventions, non-human studies, studies lacking a clear LCA methodology, or studies not reporting emissions per defined unit (e.g., per procedure).

LCAs are used to quantify or compare the environmental impact of processes or products. The most methodological complete LCA involves analysis of the “cradle-to-grave” impact of individual items, including the raw material extraction and production, transport, usage, and end-of-life (including cleaning and sterilization and waste disposal). LCAs may vary significantly because of context-specific influences, such as source of energy, waste processing methods, (efficacy of) hospital logistics, travel distance, hospital volume, and treatment protocols. LCAs can be compared and used for environmental decision-making; however, they lack broad applicability based on the context-specific factors, thus comparison should be warranted. Moreover, LCAs are time and resource demanding. Tools like the ECOMIS calculator could be the key for accessible and broadly applicable assessment of the environmental impact, thereby supporting sustainable decision-making by suggesting environmental improvements, potentially reducing costs, resource use and waste without compromising healthcare outcomes.

From the included studies, variables contributing to carbon emissions will be extracted, categorized, and evaluated based on (1) magnitude of environmental impact and (2) potential modifiability in clinical practice. Variables will be compared based on CO2-eq per procedure. To maintain usability and accessibility, the ten most relevant variables will be selected for inclusion in the sustainability calculator. A preliminary version of the calculator will be developed incorporating these variables. Internal validation will be conducted within hospitals affiliated with the ECOMIS research group to assess feasibility, accuracy, and reproducibility in real-world surgical settings. Feedback obtained during structured online meetings will be used to iteratively refine the calculator.

Phase II: Delphi study within the ECOMIS expert Steering Committee
Phase II aims to optimize the applicability, usability, and clinical relevance of the calculator through expert consensus, following the ACCORD and CREDES recommendations for consensus studies. A modified Delphi methodology will be used to ensure anonymity and iterative feedback. The process will consist of two predefined electronic survey rounds, with the possibility of up to two additional rounds if consensus is not achieved. Surveys will be administered using Castor Electronic Data Capture (EDC), and all responses will be collected anonymously.

An international expert Steering Committee will be convened, consisting of recognized experts in hepatopancreatobiliary surgery, general surgery, environmental sciences, and healthcare sustainability. Experts will be recruited through professional networks within the European Association for Endoscopic Surgery (EAES) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Invitations will be issued by the ECOMIS study team.

The Delphi questionnaire will be structured across four predefined domains: (1) feasibility, (2) user-friendliness, (3) comprehension, and (4) constraints. Depending on item characteristics, responses will include five-point Likert scales (ranging from strongly agree to strongly disagree), dichotomous responses (agree/disagree), numerical inputs, and free-text comments. The questionnaire will be developed in English. The complete survey tool will be provided as supplementary material.

After each round, quantitative responses and free-text comments will be reviewed and thematically analyzed by the ECOMIS study team. Suggested modifications will be incorporated into subsequent rounds where appropriate.

Consensus will be defined a priori as ≥80% agreement among participating experts, a threshold commonly applied in Delphi studies. To ensure result stability, items reaching consensus must retain consensus in a subsequent round following any revisions.

Statistical analysis:
Cronbach's alpha (α) will be calculated per domain for internal consistency between the experts. A value of ≥0.80 is defined as the cut-off value for determining consensus. Box plots will be constructed showing the median, interquartile range (IQR), maximum, minimum, and mean of the items. The IQR for agreeability of 1 or less on a 5-item Likert scale can be considered as consensus. All analyses will be performed using R (version 3.6.1 or higher). Statistical significance will be defined as $P<0.05$ (two sided) for all analyses.

Phase III: External validation of the calculator
Phase III will consist of a multicenter external validation study to assess the generalizability, accuracy, and clinical utility of the calculator. Participating centers will include academic and non-academic hospitals performing minimally invasive cholecystectomy across different healthcare systems. For the external validation, the ECOMIS project will collaborate with the Creating A healthieR Environment for FutuRE patiEnts (CAREFREE) project, under the supervision of Prof. Dr Nicole Bouvy.

The CAREFREE project currently investigates the carbon footprint of minimally invasive cholecystectomies in various European centers using LCA analysis. This data supports the broad applicability of the present study since it includes different countries, and hospitals.

Validation Objectives:
Criterion validity: Agreement between calculator-estimated emissions and reference LCA-derived emissions.
Calibration: Assessment of systematic over- or underestimation across emission ranges.

Statistical Analysis:
Agreement between predicted and observed emissions will be assessed using intraclass correlation coefficients (ICC) and Bland–Altman plots. Calibration will be evaluated using regression analysis and calibration plots. Discriminative performance will be assessed using quantile-based comparisons. Sensitivity analyses will be performed across hospital types and geographic regions. Missing data will be handled using multiple imputation where appropriate.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Agreement between calculator-estimated emissions and reference-derived LCA emissions measured using intraclass correlation coefficient at external validation

2. Agreement between calculator-estimated emissions and reference-derived LCA emissions measured using Bland–Altman plots at external validation

Key secondary outcome(s))
1. Consensus measured using Cronbach's alpha at Delphi consensus study

Completion date
01/07/2027

Eligibility

Key inclusion criteria
The Delphi consensus study participants will be recruited through professional networks within the European Association for Endoscopic Surgery (EAES) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Experts still in training or specialization
2. Lack of experience (<2 years) with minimally invasive cholecystectomies
3. Experts not involved in the medical care, logistical or product pathway of minimally invasive surgery

Date of first enrolment
01/04/2026

Date of final enrolment
01/04/2027

Locations

Countries of recruitment
United Kingdom

England

Malta

Netherlands

Poland

Spain

Study participating centre
Health and Care Academy
Unit 4
Northumbria Health & Care Academy
Northumbria Way
Cramlington
England
NE23 6NZ

Study participating centre
Amsterdam UMC
De Boelelaan 1117
Amsterdam
Netherlands
1081HV

Study participating centre
Mater Dei Hospital
Malta

Study participating centre
Consorci sanitari Integral
Spain

Study participating centre
Olsztyn Municipal Hospital
Poland

Sponsor information

Organisation
European Association for Endoscopic Surgery

ROR
https://ror.org/015wndh26

Funder(s)

Funder type

Funder Name
European Association for Endoscopic Surgery and other Interventional Techniques

Alternative Name(s)
European Association for Endoscopic Surgery, EAES

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.3	12/03/2026	13/03/2026	No	No