Laparoscopic versus Open Ventral Hernia repair using a classical versus Collagen MESH (Surgisis Gold®): a European Multicenter Two Factorial Randomized Controlled Trial (LAPSIS Trial)

Submission date	Recruitment status	Prospectively registered
22/06/2005	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
15/09/2005 Last Edited	Stopped Condition category	[X] Results
		Individual participant data
18/12/2020	Surgery	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Marc Miserez

Contact details

Herestraat 49 Leuven Belgium 3000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

KKSK-4711

Study information

Scientific Title

Laparoscopic versus Open Ventral Hernia repair using a classical versus Collagen MESH (Surgisis Gold®): a European Multicenter Two Factorial Randomized Controlled Trial (LAPSIS Trial)

Acronym

LAPSIS

Study objectives

- 1. Surgisis Gold (perforated) is non-inferior as compared to conventional meshes
- 2. Laparoscopic is superior to open ventral hernia repair in regards of the development of major complications

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 30/09/2013: Medical Ethics Committee of the UZ KULeuven, 17/01/2005, ref: ML2925

Study design

Multicenter two factorial randomised controlled trial

Primary study design

Interventional

Secondary study design

Multi-centre

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Primary or incisional ventral hernia

Interventions

Collagen mesh (Surgisis Gold® [perforated]) versus conventional mesh and laparoscopic versus open ventral hernia repair.

Updated 10/09/2009: this trial has stopped recruiting and the last patient was randomised on 21 /07/2009. Follow-up is ongoing for the next three years and the date of last patient out (LPO) is anticipated for August 2012. The anticipated end date of this trial was changed from 31/05/2009 to reflect this.

Updated 13/09/2013: follow-up has ended and the database has been locked.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

Major complication (hernia recurrence, prosthetic infection, re-operation) rate within three years after surgery

Secondary outcome measures

- 1. Early (first 30 days postoperatively) and late (up to three years postoperatively) local complication rate (wound infection, wound dehiscence, wound sinus, fistula formation, bleeding, hematoma, seroma formation, peritonitis, mechanical obstruction, ileus, other)
- 2. Early (first 30 days postoperatively) general complication rate (all adverse events other than listed under local complications: thromboembolic events, cardiac, respiratory, other)
- 3. Time to failure (= major complication)
- 4. Chronic abdominal wall pain (Von Korff chronic pain questionnaire; preoperatively, one and three years postoperatively
- 5. Chronic discomfort e.g. abdominal wall stiffness (visual analogue scale [VAS]; preoperatively and three years postoperatively)
- 6. Mortality (up to three years postoperatively)
- 7. Incidence of and cause for conversion in the laparoscopy group

Overall study start date

01/07/2005

Completion date

31/08/2012

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

- 1. Elective repair of ventral (including umbilical) hernia with need for mesh repair
- 2. Age ≥18 years
- 3. Male and female patients may participate
- 4. Minimal hernia orifice diameter ≥4 cm
- 5. Largest hernia orifice ≤10 cm
- 6. Eligibility to laparoscopic mesh repair
- 7. Written informed consent.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

660

Total final enrolment

253

Key exclusion criteria

- 1. Medical or surgical contraindication to general anesthesia
- 2. Severe comorbidity (American Society of Anesthesiologists [ASA] physical status classification ≥4)
- 3. Pregnancy
- 4. Emergency surgery for incarcerated irreducible hernia
- 5. Previous mesh repair at the same site
- 6. Hernia orifice <3 cm away from costal margin/sternum and/or pubis
- 7. Lumbar hernia
- 8. Parastomal hernia
- 9. Need for more than one mesh covering the hernia orifice
- 10. Need for a mesh larger than 20 cm x 20 cm or 22 cm x 13 cm
- 11. Crohns disease
- 12. Life expectancy less than 12 months
- 13. Chemotherapy within the last four weeks
- 14. Radiotherapy within the last two months
- 15. Previous abdominal radiotherapy
- 16. Known allergy against porcine materials
- 17. Marfans syndrome
- 18. Child B or C liver disease
- 19. Morbid obesity (body mass index [BMI] ≥40 kg/m^2)
- 20. Non-compliance
- 21. Simultaneous participation in other interventional trials interfering with one of the approaches in this trial
- 22. Previous participation in this trial

Date of first enrolment

01/07/2005

Date of final enrolment

31/08/2012

Locations

Countries of recruitment

Austria

Belgium

Croatia

Germany
Greece
Hungary
Italy

Netherlands

Denmark

Poland

Portugal

Study participating centre Herestraat 49 Leuven Belgium 3000

Sponsor information

Organisation

Individual Sponsor (Germany)

Sponsor details

Prof Dr Edmund Neugebauer Ostmerheimer Str. 200 Cologne Germany 51109

Sponsor type

Other

Funder(s)

Funder type

Industry

Funder Name

Cook Biotech Inc. (USA)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2021	18/12/2020	Yes	No