

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

<b>Submission date</b> 22/06/2005	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/09/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/12/2020	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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Herestraat 49  
Leuven  
Belgium  
3000

## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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  $\geq 18$  years
3. Male and female patients may participate
4. Minimal hernia orifice diameter  $\geq 4$  cm
5. Largest hernia orifice  $\leq 10$  cm
6. Eligibility to laparoscopic mesh repair
7. Written informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**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  $\geq 4$ )
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]  $\geq 40$  kg/m<sup>2</sup>)
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

Denmark

Germany

Greece

Hungary

Italy

Netherlands

Poland

Portugal

**Study participating centre**  
Herestraat 49  
Leuven  
Belgium  
3000

## Sponsor information

**Organisation**  
Individual Sponsor (Germany)

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Cook Biotech Inc. (USA)

## Results and Publications

**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?
<a href="#">Results article</a>	results	01/01/2021	18/12/2020	Yes	No