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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
22/06/2005

Registration date
15/09/2005

Last Edited
18/12/2020

Recruitment status
Stopped

Overall study status
Stopped

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data
[ ] 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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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

Denmark

Germany

Greece

Hungary

Italy

Netherlands

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