Efficacy and Safety of LifeSeal* Kit for Staple Line Sealing in Colorectal and Coloanal Anastomoses: A Prospective Randomized Study.

Published: 24-04-2017
Last updated: 15-04-2024

The primary objective of this study is to assess the efficacy and safety of LifeSeal* Kit as measured by the change in overall anastomotic leak rates in subjects undergoing low anterior resection with an anastomosis below 10 cm from the anal verge,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON45486

Source
ToetsingOnline

Brief title
LifeSeal Pivotal study

Condition

- Gastrointestinal therapeutic procedures

Synonym
anti-leakage, sealing

Research involving
Human

Sponsors and support

Primary sponsor: LifeBond Ltd.

Source(s) of monetary or material Support: Lifebond Ltd

Intervention

Keyword: coloanal anastomoses, colorectal anastomoses, medical device, staple line seal

Outcome measures

Primary outcome

Primary Efficacy Endpoint

- The incidence of intra-operative and postoperative (clinical and radiologic) anastomotic leaks in high risk circular stapled colorectal and coloanal anastomoses up to 17 weeks after the initial surgery.

Secondary outcome

The secondary endpoints of this study are designed to focus on the incidence of postoperative leaks and to assess the impact of a leak once it occurs in high risk stapled colorectal or coloanal anastomoses. The order of the secondary endpoints will be tested in a pre-defined order that will be specified in the study Statistical Analysis Plan.

See also paragraph 7.2 of the protocol.

Study description

Background summary

To date, there have been no randomized controlled trials powered to assess the efficacy of LifeSeal* Kit in colorectal surgery subjects and its effects on intra-operative air leaks and postoperative anastomotic leakage. The current trial is designed to confirm the efficacy and safety of LifeSeal* Kit for use in treating rectal anastomoses as part of its clinical investigation towards marketing approval in the US and to collect additional postmarketing data on

the safety and efficacy of LifeSeal* Kit in Europe.

Study objective

The primary objective of this study is to assess the efficacy and safety of LifeSeal* Kit as measured by the change in overall anastomotic leak rates in subjects undergoing low anterior resection with an anastomosis below 10 cm from the anal verge, over the first 17 weeks after surgery.

The secondary objective of this study is to assess the incidence of post-operative leaks and additional benefits that could be related to the use of LifeSeal* Kit such as reducing the severity and improving the outcome of a leak once it has occurred. In addition, the study will allow for collection and analysis of additional safety data and usability assessment of the device, medical resource utilization, and health related quality of life measures.

Study design

This study is designed as a prospective, multi-center, multinational randomized, single-blind, double armed study with either open, laparoscopic or robot assisted procedure.
The study is classified as a post marketing interventional study in Europe, and as a pre-market approval study in the USA.
The primary efficacy analysis will be performed based on data collected up to 17 weeks from application of LifeSeal*. Overall safety data will be collected up to 6 months. Additional safety assessments will continue up to two years.
The study is designed to demonstrate superiority of LifeSeal to the control with respect to the leakage rate; the LifeSeal group leakage rate must be lower than standard of care group (without LifeSeal).

Intervention

For all subjects, standard hospital protocol will be followed for surgical procedure and subject care management. This is except for a few interventional procedures required for all patients per study protocol:
1. Contrast enema assessment- for patients who receive a protective ileostomy this is considered as standard of care and is done per routine practice. For patients who do not receive a protective ileostomy, this is an additional examination per study requirements.
2. Collection of blood samples from all patients, for evaluating the immunological profile of LifeSeal* Kit.
3. Rectoscopy or digital examination to evaluate strictures at the anastomotic site
4. Pregnancy test (blood or urinary test) performed at screening for all female subjects who are in child bearing age.

5. C-Reactive protein (CRP) blood test (US sites only)

Study burden and risks

Patients will receive the routine surgery they would normally receive, only now with the 50% chance of receiving the Investigational Product LifeSeal.
After the surgery, the patients usually visit their doctor for follow-up for about 5 years. For this study, they will be asked to come follow-up visits at least 2 years, with possible extension to 5 years if requested by the FDA (in order to obtain marketing authorization in the USA).
Also the blood sampling, the contrast enema (with CT) at Visit 1, and Endoscopy are an Investigational Study Assessment and not standardly done after routine surgery.

The rest of the medical care they will receive in this study is considered routine care for their condition and would be recommended as well when not participating in the study.

See also E9 for burden and risks.

Patients may not experience direct benefits as a result of study participation. The information gained in this study may help other subjects undergoing the same surgery in the future.

Contacts

Public
LifeBond Ltd.

Halamish Street 9
Industrial Park Caesarea 3088900
IL
Scientific
LifeBond Ltd.

Halamish Street 9
Industrial Park Caesarea 3088900
IL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Male or female * 21 years of age at Screening Visit.
2. Written informed consent obtained from subject or subject*s legal representative and ability for subject to comply with the requirements of the study.
3. Subject is diagnosed with colorectal cancer
4. Subject is scheduled for elective open, laparoscopic or robot assisted surgery involving the creation of a circular stapled anastomosis created within 10cm from the anal verge.
5. Procedure involving Total Mesorectal Excision by an abdominal or transanal approach.
6. Female subjects in child bearing age must be using acceptable contraception methods such as hormonal contraception or two forms of barrier contraception. Acceptable contraception must be used consistently from 30 days before screening until 3 years following surgery.

Exclusion criteria

Pre-operative exclusion criteria:
1. Female subject who is pregnant, breastfeeding, or if of child bearing potential is unwilling to practice birth control until 3 years following surgery.
2. Presence of a condition or abnormality that in the opinion of the Investigator would compromise the safety of the subject or the quality of the data.
3. Subject has a history of hypersensitivity to porcine derived gelatin or collagen.
4. Subject has a history of hypersensitivity to microbial Transglutaminase.
5. Subject has a known dysfibrinogenimeia, hypofibrinigenimia or a fibrinogenimia, without preoperative correction of fibrinogen levels.
6. Subject participating in any other study involving an investigational (unapproved) drug or device within the past 60 days.
7. Subject participating in studies involving approved drug or device will be enrolled only following a mutual consideration of the investigator together with the Sponsor.
8. Subject with a BMI *50, which may interfere with access to the surgical site and increase overall operative risk.
9. Subject with American Society of Anesthesiology (ASA) status higher than 3.
10. Avastin use within 30 days prior to surgery.

11. Subject who has undergone a prior pelvic anastomosis.
12. Subject is scheduled for another surgery during the first 6 months following surgery (not including stoma closure,placement of port for chemotherapy or ureter stent insertion).
13. Subject with an active abdominal or pelvic infection at the operation site.
14. Subject has been previously treated with LifeSeal* Surgical Sealant.;Intra-operative Exclusion Criteria
1. Anastomosis or procedure (TME) was performed differently from what was defined in the inclusion criteria.
2. Subject received intra-operative sealant, glue or any buttressing material other than the LifeSeal* Surgical Sealant.
3. Subject has peritoneal carcinomatosis.
4. Subject requires additional unrelated anastomosis during the surgery.
5. Subject is going through another surgical procedure (other than ileostomy or adhesiolysis) during the surgery.
6. Excessive bleeding (above 500cc) identified prior to anastomosis formation with the need for intra-operative blood transfusion.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2017
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	LifeSeal
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-04-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-02-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02907385
CCMO	NL59073.100.16