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Bioabsorbable staple line reinforcement in circular stapling device to reduce the incidence of anastomotic leak following rectosigmoid resection

Submission date 06/11/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/11/2008	**Overall study status** Completed	
Last Edited 11/05/2016	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title
Bioabsorbable staple line reinforcement in circular stapling device is effective in reducing the incidence of anastomotic leak following rectosigmoid resection: a case control study

Acronym
STAPLE

Study objectives
The incidence of anastomotic leak after colorectal resection has been quoted from 7% to 14%. Anastomotic leak despite the development of modern techniques for colonic anastomosis is still one of the most devastating phenomenon in colorectal surgery. It is associated with significant increase in mortality-morbidity and a permanent stoma. Methods have been employed to reduce the anastomotic leak and include reinforcement suturing after the use of circular stapling device and the use of bioabsorbable staple line reinforcement.

Hypothesis:
There is no difference in the incidence of anastomotic leak in patients undergoing anterior resection using bioabsorbable reinforcement with a circular stapling device for colorectal or colocolic anastomosis compared with those without reinforcement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Brighton Research Ethics Committee; pending as of 06/11/2008.

Primary study design
Interventional

Study design
Interventional non-randomised controlled pilot trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anastomotic leak following rectosigmoid resection

Interventions
Bioabsorbable staple line reinforcement for circular stapler (GORE SEAMGUARD®). Disc will be incorporated between the two ends of circular stapling device before firing for anastomosis. First four procedures will be supervised and assisted by the medical representative from Gore. Procedures will be performed by Consultant Colorectal Surgeons and assisted by surgical registrars. All procedures will be video recorded. The controls (25 subjects) will be from the previous 12 months with no reinforcement.

Total duration of follow-up: one year.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)

Thirty-day anastomotic leak confirmed by clinical presentation, raised inflammatory markers, and /or ultrasonography of abdomen and pelvis and/or water soluble contrast enema and/or computerised tomography of abdomen and pelvis with or without contrast.

Key secondary outcome(s)
1. Associated co-morbidities which might influence the anastomotic healing. This will be assessed on a daily basis or as per clinical requirements whilst an in-patient and then three-monthly for one year.
2. Operative time
3. Blood loss
4. Post-operative complications. This will be assessed on a daily basis or as per clinical requirements whilst an in-patient and then three-monthly for one year.
5. Re-operation. Total duration of follow-up: one year.
6. Total hospital stay. Total duration of follow-up: one year.
7. Thirty-day mortality

Completion date
01/12/2009

Eligibility

Key inclusion criteria
1. Patients with rectosigmoid pathology undergoing anterior resection or sigmoid colectomy with primary end to end colorectal anastomosis with or without defunctioning ileostomy
2. Patients of either sex
3. Patients of all age groups
4. Patients of any body mass index (BMI)
5. Patients undergoing elective surgery
6. Those patients will also be included who have had neoadjuvant radiotherapy or chemoradiotherpay for rectosigmoid tumours
7. Patients of American Society of Anaesthesiologists (ASA) I, ASA II and ASA III anaesthetic risks
6. Patients who agree and sign the consent to participate in this study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Patients unable to give consent or refuse to participate in this study
2. Patients undergoing procedure on Confidential Enquiry into Patient Outcome and Death

(CEPOD) list as an emergency
3. Patients undergoing procedure as a post-operative complication
4. Re-do procedure

Date of first enrolment
01/12/2008

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Worthing Hospital
West Sussex
United Kingdom
BN11 2DH

Sponsor information

Organisation
Sussex NHS Research Consortium

Funder(s)

Funder type
Government

Funder Name
Sussex NHS Research Consortium (UK)

Funder Name
W. L. Gore & Associates, Inc. (USA) - donation of 5/25 samples

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration