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Prevention of post-operative pelvic bleeding and collection after sphincter-saving surgery for rectal cancer using a calcium-alginate haemostatic

Submission date 09/03/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/03/2009	**Overall study status** Completed	
Last Edited 11/03/2010	**Condition category** Cancer	

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
N/A

Study information

Scientific Title
Prevention of post-operative pelvic bleeding and collection after sphincter-saving surgery for rectal cancer using a calcium-alginate haemostatic: a multicentric randomised study

Study objectives
Assess the possible benefit of Hemoionic®, a new haemostatic, in sphincter-saving surgery for rectal cancer with special reference to pelvic fluid collection reduction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. French ethics committee (Comité Consultatif de Protection des Personnes dans la Recherche Biomédicale [CCPPRB]) approved on 4th January 2006 (ref: 0511240)
2. French drug administration (Agence Française de Sécurité Sanitaire des Produits de Santé [AFSSAPS]) approved on 6th January (ref: 2005/12/007)

Study design
Multicentre prospective randomised parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Rectal cancer/colorectal surgery

Interventions
Resections were performed according to the standard technique of optimal mesorectal excision (either partial or total according to the level of the rectal tumour) either by laparotomy or laparoscopy. Complete pelvic haemostasis was obtained prior to randomisation, according to the surgeons' routine practice, with electrical coagulation and/or vessel ligation. Randomisation was performed during the surgical procedure in a 1:1 ratio to an Hemoionic® group or a control group.

After complete pelvic hemostasis, patients randomised in the Hemoionic® group had two applications of Hemoionic® in the sacral cavity for at least 5 and 10 minutes respectively.

For the Hemoionic® group a proctectomy with partial mesorectal excision and stapled colorectal anastomosis was performed for tumours of the upper rectum. A proctectomy with total mesorectal excision was performed for tumours of the middle and lower rectum. Anastomosis was performed mechanically or manually, according to the level of the anastomosis. Pelvic drainage was standardised for all procedures as an aspirative cross-perforated redon drain (from 10 to 14 ch.) placed in the pelvic cavity, behind the anastomosis. A temporary stoma was systematically fashioned at the end of the operation.

For the control group the same surgery was perfomed without using any other haemostatic.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hemoionic®

Primary outcome measure
Volume of fluid collected by the pelvic suction drain.

Secondary outcome measures
1. Duration of drainage
2. Post-operative mortality and morbidity rates 3 months after surgery

Overall study start date
20/04/2006

Completion date
23/08/2007

Eligibility

Key inclusion criteria
1. Written informed consent from all patients at least the day before surgery
2. Patients aged 18 years or older, either sex
3. Scheduled for elective restorative proctectomy for rectal cancer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
84

Key exclusion criteria
1. Advanced local disease (tumour staged T4 on pre-operative rectal ultrasound, magnetic resonance imaging, or intra-operative findings)
2. No temporary protective ileostomy or colostomy after rectal resection
3. Anticoagulation or antiplatelet treatment which cannot be postponed for surgery
4. Known associated haemostasis disorder
5. Synchronous other surgical resection (excepted appendectomy and liver biopsy)
6. Emergency presentation
7. Systemic infection
8. Pelvic infection
9. Pregnancy

Date of first enrolment
20/04/2006

Date of final enrolment
23/08/2007

Locations

Countries of recruitment
France

Study participating centre
Service de Chirurgie colorectale - Hôpital Beaujon
Clichy
France
92118

Sponsor information

Organisation
Brothier Laboratories S.A. (France)

Sponsor details
41 Rue de Neuilly
Nanterre
France
92735

Sponsor type
Industry

ROR
https://ror.org/007jkh405

Funder(s)

Funder type
Industry

Funder Name
Brothier Laboratories S.A. (France)

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	01/04/2010		Yes	No