

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

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		<input type="checkbox"/> Protocol
Registration date 27/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/03/2010	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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 performed without using any other haemostatic.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Hemoionic®

Primary outcome(s)

Volume of fluid collected by the pelvic suction drain.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/007jkh405>

Funder(s)

Funder type

Industry

Funder Name

Brothier Laboratories S.A. (France)

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?
Results article	results	01/04/2010		Yes	No