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Interrupted or continuous slowly absorbable Sutures - Evaluation of abdominal Closure Techniques

Submission date	Recruitment status	[X] Prospectively registered
03/02/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/03/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2012	Surgery	

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
KSC 04/2003

Study information

Scientific Title

Acronym
INSECT-Trial

Study objectives
Patients undergoing primary median laparotomy for an elective surgical intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The final protocol was approved by the ethics committee of the University of Heidelberg, Medical School.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Abdominal surgery

Interventions
A standardised surgical approach for opening of the abdomen is performed in all patients with a midline incision of at least 15 cm length.

The randomisation will proceed when the operation has been finished and the abdominal wall cavity should be closed. The treatment groups are:
1. Two continuous groups use the same technique with a 4 to 1 ratio (suture to incision length)
2. Two loops will be used in each patient and tied together in the middle of the incision
3. One interrupted suture group: vicryl sutures are used with standard pointed needles

The stitches are performed from the cranial end to the middle of the incision and then from the caudal end also to the middle of the incision. Once all the stitches are made, each suture is tied with at least four knots. The subcutaneous tissue is not sutured and no subcutaneous drainage is used in all patients. The skin is closed with clips or single stitches of a non-absorbable monofilament suture material. The postoperative treatment is standardised.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
The frequency of incisional hernias between three different abdominal fascia closure methods after one year postoperatively.

Key secondary outcome(s)
Frequencies of early and late onset complications such as burst abdomen, postoperative pulmonary complications, wound infections and incisional hernias after three years postoperatively.

Completion date
31/08/2007

Eligibility

Key inclusion criteria
1. Aged equal or greater than 18 years
2. Expected survival time more than 12 months
3. Patients undergoing primary and elective median laparotomy (patients with prior laparoscopy or abdominal operation via paramedian incision (e.g. appendectomy) may be included in the trial)
4. Body mass index (BMI) less than 35
5. Expected length of incision greater than 15 cm
6. Patient must be able to give informed consent
7. Patient has given informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Peritonitis
2. Emergency surgery
3. Participation in another intervention-trial with interference of intervention and outcome of this study
4. Coagulopathy: a group of disorders of the blood clotting (coagulation) system in which bleeding is prolonged and excessive with abnormal values in the blood laboratory
5. Severe psychiatric or neurologic diseases
6. Lack of compliance
7. Drug- and/or alcohol-abuse according to local standards
8. Current immunosuppressive therapy (more than 40 mg of a corticoid per day or azathioprin)
9. Chemotherapy within 2 weeks before operation
10. Radiotherapy of the abdomen completed longer than 8 weeks before operation

11. Inability to follow the instructions given by the investigator or the telephone interviewer (insufficient command of language, dementia, lack of time)
12. Lack of informed consent

Date of first enrolment
01/07/2004

Date of final enrolment
31/08/2007

Locations

Countries of recruitment
Germany

Study participating centre
Im Neuenheimer Feld 110
Heidelberg
Germany
69120

Sponsor information

Organisation
BBD Aesculap GmbH (Germany)

ROR
https://ror.org/04nxj7050

Funder(s)

Funder type
Industry

Funder Name
BBD Aesculap GmbH (Germany)

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	01/04/2009		Yes	No
Results article	results	08/02/2012		Yes	No
Protocol article	Protocol	08/03/2005		Yes	No
Other publications	Sub-study on the ethical review process	01/02/2007		Yes	No