

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

<b>Submission date</b> 03/02/2004	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 08/03/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/02/2012	<b>Condition category</b> Surgery	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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.

## Study design

Randomised controlled 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

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 measure**

The frequency of incisional hernias between three different abdominal fascia closure methods after one year postoperatively.

### **Secondary outcome measures**

Frequencies of early and late onset complications such as burst abdomen, postoperative pulmonary complications, wound infections and incisional hernias after three years postoperatively.

### **Overall study start date**

01/07/2004

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

## **Target number of participants**

600

## **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)

### **Sponsor details**

Am Aesculap Platz

Tuttlingen

Germany  
78532

**Sponsor type**  
Industry

**ROR**  
<https://ror.org/04nxj7050>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
BBD Aesculap GmbH (Germany)

## 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?
<a href="#">Protocol article</a>	Protocol	08/03/2005		Yes	No
<a href="#">Other publications</a>	Sub-study on the ethical review process	01/02/2007		Yes	No
<a href="#">Results article</a>	results	01/04/2009		Yes	No
<a href="#">Results article</a>	results	08/02/2012		Yes	No