PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

**Prophylactic Mesh Implantation
after Abdominal Aortic Aneurysm Repair.
A prospective, randomised, controlled study.**

Trial Acronym

AIDA (Abdominal Incision Defect following AAA Surgery)

URL of the trial

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Brief Summary in Lay Language

A frequent late complication of elective open abdominal aortic aneurysm surgery is the formation of an incisional hernia following the surgical intervention.

AIDA Study underlies the hypothesis that the herniation rate could be reduced by the prophylactive implantation of a surgical mesh.

On actually ten sites all over Germany 282 patients undergoing an elective open aortic aneurrysm repair arel entered into the clinical investigation.

Brief Summary in Scientific Language

AIDA Study is a prospective, multicentre, randomized, controlled clinical investigation with patients undergoing median laparotomy for elective Abdominal Aortic Aneurysm (AAA) repair.

The primary objective of the clinical investigation is to test the hypothesis that insertion of an Optilene® Mesh Elastic mesh - a monofilament, light-weight, large pore sized, polypropylene mesh manufactured by Aesculap AG - is superior to suturing alone and will reduce the hernia formation rate within the first 2 years.

A reduction from 30% to 10% of the patient population is assumed.

The high frequency of incisional hernia formation in the AAA patients suggests the presence of a structural defect within the fascia.

As a result of these information and that obtained from a small pilot study using mesh prophylactically in high risk group of patients, the concept of using a mesh prophylactically for AAA repairs seems an area worth further exploration.

Owing to the availability of the new generation of meshes with proven good biocompatibility it would seem that this could be a viable means of reducing the

herniation rate and therefore re-operation in this high risk population.

Within the investigation Patients requiring elective surgical repair of an AAA will be randomized in one of the following three different groups:

Group A: Monofilament absorbable MonoPlus® suture material will be used for closing of the midline incision.

Group B: Abdominal wall closure with monofilament absorbable MonoPlus® suture material and onlay placement of Optilene® Mesh Elastic fixed by sutures.

Group C: Monofilament, absorbable MonoMax® suture material will be used for the closure of the abdominal cavity.

A total of 282 patients who meet the eligibility criteria will be entered into the clinical investigation (Group A = 94 patients, Group B = 94 patients and Group C = 94 patients).

All patients will have follow-up clinical visits 2 days after surgery, at day of discharge, at 3, 6, and 12 months and a final visit at 24 months. All patients will be asked to complete the health status patient questionnaire EQ-5D preoperatively and at 3, 6, 12 and 24 months postoperatively. As all patients routinely receive an ultrasound at 3, 6, 12, and 24 months, this information will be used to confirm if a hernia is present.

Organizational Data

- DRKS-ID: **DRKS00003379**
- Date of Registration in DRKS: **2011/12/06**
- Date of Registration in Partner Registry or other Primary Registry: **2011/04/18**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **PV3405 , Ethik-Kommission der Ärztekammer Hamburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1126-2554**
- Primary Registry-ID: **NCT01353443 (ClinicalTrails.gov)**

Health condition or Problem studied

- ICD10: **I71.4 - Abdominal aortic aneurysm, without mention of rupture**
- Free text: **Abdominal Aortic Aneurysm**

Interventions/Observational Groups

- Arm 1: **Monofilament absorbable MonoPlus® suture material will be used for closing of the midline incision.**
- Arm 2: **Abdominal wall closure with monofilament absorbable MonoPlus® suture material and onlay placement of Optilene® Mesh Elastic fixed by sutures.**
- Arm 3: **Monofilament, absorbable MonoMax suture material will be used for the closure of the abdominal cavity.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Active control**
- Purpose: **Supportive care**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Herniation rate 24 months after Intervention (verified by clinical examination and confirmed by Ultrasound).

Secondary Outcome

1. Lower herniation rate in the 12 months after mesh implantation in group B as compared to group A.

2. Non-inferiority of MonoMax suture material (group C) in comparison to MonoPlus suture material (group A) concerning the rate of incisional hernia after abdominal wall closure at 3, 6, 12, and 24 months after surgery.

3. Mean time, in days, to return to normal activities as determined by CRF question (comparison of groups A, B, C).

4. Mean time, in days, to return to work as determined by CRF question (comparison of groups A, B, C).

5. Differences in mean patient health status as determined by using a patient questionnaire (EQ-5D) at 3, 6, 12 and 24 months post-operatively; pre-operative baseline will be recorded (groups A-C).

6. Number of wound complications (groups A-C) as determined by medical assessment post-operatively immediately prior to discharge, and at the clinical visits at 3, 6, 12 and 24 months, including infections, seromas, haematomas, and

hernia formation, confirmed by ultrasound examination.

7. Safety as determined by collection of adverse events in the CRF (groups A-C).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinikum Hamburg-Eppendorf, Hamburg**
- Medical Center **Klinikum rechts der Isar der TU München, München**
- University Medical Center **Universitätsklinikum Würzburg, Würzburg**
- University Medical Center **Universitätsklinikum Aachen, Aachen**
- Medical Center **Klinikum Nürnberg Süd, Nürnberg**
- Medical Center **Klinikum Stuttgart - Katharinenhospital, Stuttgart**
- Medical Center **Klinikum Bremen Nord, Bremen**
- Medical Center **Asklepios Klinik Altona, Hamburg**
- Medical Center **Asklepios Klinik Wandsbek, Hamburg**
- Medical Center **Asklepios Klinik Harburg, Hamburg**
- Medical Center **Klinikum Ludwigsburg, Ludwigsburg**
- Medical Center **Universitätsklinikum Heidelberg, Heidelberg**
- Medical Center **SRH Klinikum Karlsbad-Langensteinbach, Karlsbad**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/02/23**
- Target Sample Size: **108**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1. Male and female patients >18 years of age.

2. Patients undergoing an elective surgery for AAA repair.

3. Patients who currently have no malignant disease requiring therapy.

4. Patients who are able to fulfill all clinical investigation requirements

5. Patients who have provided written informed consent.

Exclusion criteria

1. Patients who require median laparotomy for AAA repair as an emergency procedure.

2. Expected length of fascia incision > 30 cm.

3. Patients with coagulopathy

4. Patients who have had previous median laparotomy and/or laparaotomy crossing the incision necessary for AAA laparotomy.

5. Patients with current immunsuppressive therapy (>40 mg corticoid/day or azathioprine).

6. Chemotherapy within the last 4 weeks.

7. Radiotherapy on the treated region within the last 2 months.

8. Pregnant and breast-feeding women.

9. Known allergy against ingredients of the investigational products (polypropylene, poly-4-hydroxybutyrate, polydioxanone).

10. Patients participating in other investigational drug or medical device studies within the preceding 4 weeks.

11. Patients with an ongoing medical condition or social reason that may affect their ability to complete the two years follow-up period.

12. Life expectancy less than 24 months.

13. Severe psychiatric or neurologic disease.

14. Lack of compliance.

15. Drug abuse.

16. Inability to understand and follow the instructions given by the investigator (e.g. dementia, lack of time, insufficient command of language).

Addresses

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

  Aesculap AG
  B. Braun Surgical
  Ms. Dr. Petra Baumann

Commercial (pharmaceutical industry, medical engineering industry, etc.)

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Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*