PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Clinical Study Into the Cosmetic Results of Leukosan Adhesive vs. Transcutaneous Wound Suture With Laparoscopic Trocar Incision

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This clinical study aims to assess whether the benefits of using Leukosan Adhesive on trocar incisions are greater or equivalent to those provided by the standard therapy of transcutaneous sutures.

In particular, it tests the long-term cosmetic result after 3 months, the safety and tolerance, as well as the practicality of treatment with Leuksan Adhesive.

An open, randomised, controlled, prospective, single location, clinical study of women of ages between 18 and 60 years within the time span of March 2013 and April 2013.

Brief Summary in Scientific Language

The medical devices compared were EU (European Union) approved market-ready products with relevant designation according to the legal requirements for medical devices and according to Council guideline 93/42/EWG dated 14th July.

Leukosan Adhesive is a sterile, ultra high viscose adhesive for external skin closure. Due to the skin's moisture, this skin adhesive polymerizes within seconds into a flexible film firmly holding the edges of the wound together and protecting the wound itself.

Premilene DSMP 24, 3/8 needle, thread 3/0 denier was used a comparison. This suture material was the standard suture material used in the study centre.

Organizational Data

- DRKS-ID: **DRKS00008338**
- Date of Registration in DRKS: **2016/02/19**
- Date of Registration in Partner Registry or other Primary Registry: **2014/06/30**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02179723 (ClinicalTrials.gov)**
- Sponsor-ID: **BSNMedicalC09962 (Dr. Stephanie Krause)**
- Other Secondary-ID: **PV4003**

Health condition or Problem studied

- Free text: **Wound Healing Cosmetic Result**

Interventions/Observational Groups

- Arm 1: **Device: Leukosan Adhesive**
- Arm 2: **Device: Transcutaneous suture**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **patient/subject, caregiver, investigator/therapist**
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
-

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Single arm study**

Blinding: **[---]***

Who is blinded: **patient/subject, caregiver, investigator/therapist**

Control: **Uncontrolled/Single arm**

Purpose: **Treatment**

Assignment: **Single (group)**

- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Patient's satisfaction with cosmetic appearance/result of the wound; time frame: 3 months post operation; The primary outcome was the satisfaction of the patients with the cosmetic result of the wound healing after 3 months. This was measured by a visual analogue scale. In order to validate this result, an additional known wound assessment instrument, an ordinal scaled index, was implemented and the assessment of independent assessors was called on.

Secondary Outcome

- The incidence of complication; time frame: 7-12 days post-operation; 7-12 days post-operation patients were examined for complications in treatment such as wound dehiscence, maceration, redness, overheating and pain
- Intensity of pain; time frame: 7-12 days post-operation; 7-12 days post-operation patients were examined for intensity of pain
- Investigator's assessment of cosmetic outcome; time frame: At 3 months post-operation; The Investigator examined patients to assess the cosmetic outcome.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Tagesklinik Altonaer Strasse, Hamburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2012/03/31**
- Target Sample Size: **77**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

- Female between 18 and 60

- Undergone laparoscopic operation with 2 mirror image trocar incisions

- Willing to attend examination at clinic at 7-12 days and 10-14 weeks

- Signed agreement by participant

Exclusion criteria

- Length of laparoscopic operation more than 2 hours

- Hospitalisation due to complications

- Circumstances leading to difference in trocar incisions

- Existing scar less than 3 cm from the operation point

- Diabetic condition melitis HbA1c>9mg/d

- Known allergy to tissue adhesive

- Participation in another study within 30 days

Addresses

- **Primary Sponsor**

  Dr. Stephanie Krause

Primary Sponsor

Dr. Stephanie Krause

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Contact for Scientific Queries**

Tagesklinik Altonaer Strasse
Olaf Buchweitz, Priv.Doz.

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URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/07/01**

Trial Publications, Results and other documents

- Further trial documents **Rosen DM, Carlton MA. Skin closure at laparoscopy. J Am Assoc Gynecol Laparosc. 1997 May;4(3):347-51.; 9154784**
- Further trial documents **Matin SF. Prospective randomized trial of skin adhesive versus sutures for closure of 217 laparoscopic port-site incisions. J Am Coll Surg. 2003 Jun;196(6):845-53.; 12788419**
- Further trial documents **Buchweitz O, Wülfing P, Kiesel L. A prospective randomized trial of closing laparoscopic trocar wounds by transcutaneous versus subcuticular suture or adhesive papertape. Surg Endosc. 2005 Jan;19(1):148-51. Epub 2004 Nov 18.; 15549624**
- Further trial documents **Schuirmann DJ. A comparison of the two one-sided tests procedure and the power approach for assessing the equivalence of average bioavailability. J Pharmacokinet Biopharm. 1987 Dec;15(6):657-80.; 3450848**