# Trial Description

## Title

**Randomised controlled study to evaluate the efficacy of the treatment of Iatrogenic Subcutaneous Abdominal Wounds (ISAW) after surgery by application of Negative Pressure Wound Therapy (NPWT) in comparison to Standard Conventional Wound Therapy (SCWT) of the clinical routine**

## Trial Acronym

**ISAW**

## URL of the trial

**http://www.wound-care.de**

## Brief Summary in Lay Language

**The Institute for Research in Operative Medicine as part of the Private University of Witten
/Herdecke is performing a clinical study project to evaluate the efficacy of NPWT for the treatment of postsurgical abdominal wound healing impairments after abdominal surgery. Thereby a comparison between NPWT and SCWT will be drawn.**

**The main target parameters, time till complete wound closure and number of wound closures among ca. 250 patients during the maximum treatment time of 42 days, the recurrence of wound healing impairments and the changes of wound sizes during course of time will be documented photographically and by computer-based analysis.**

**Patients with preliminarily closed abdominal wounds, which experience a spontaneous reopening after surgery or with wound healing disorder in the postoperative course or whose wounds will be reopened by the physician in charge will be enrolled in the study. Patients whose wounds can not be closed initially and need further treatment to achieve wound closure will be enclosed in the study likewise. Study therapy will be started with inpatient treatment and will be continued outpatient care, if necessary. Patients with acceptable general condition should be assigned to ambulant treatment as soon as possible.**

## Brief Summary in Scientific Language

**Conduct of a study project with the intention to prove the efficacy and the benefit of NPWT in patient-centered care of ISAW in inpatient and outpatient therapy.**

**This study project evaluates the therapeutic outcome of the application of a CE-certified technical medical product, based on the principle of the NPWT (intervention group) in comparison to the SCWT of the control group for the treatment of subcutaneous abdominal wound-healing impairments without fascial dehiscence after surgical interventions und will be conducted in medical departments, which offer special structural, personal and scientific qualifications. Negative pressure devices of two companies acting nationwide, whose systems**

**are CE-certified and field-tested, will be applied.**

**Patients will be stratified according to the assignment to the participating facility (clinic) und according to their wound sizes. Study therapy will be started in hospital and should be continued in an out-patient setting. This clinical trial is designed as a national multi-centric prospective randomised controlled superiority study. The planned number of study centres is 25.**

**Aim of the study is the comparison of clinical, safety and economic results of NPWT and SCWT in the treatment of postoperative wound-healing impairments without fascial dehiscence. Primary endpoints are the time till complete wound closure within the maximum treatment period of 42 days (lasting for 30 days) and the number of wound closures of each study arm within 42 days. In addition, this study contains the detailed recording of specific covariates and their influences on target parameters.**
**A blinded computer-based analysis of wound photographs with focus on the primary endpoints (complete wound closure and number of wound closures) and secondary endpoints (changes of wound sizes in the course of time, number of relapses) will be performed.**

**The study is based on the hypothesis that the application of NPWT for treatment of postoperative abdominal wound-healing impairments with intact fascia results in a decrease of time until achievement of wound closure (with confirmation after 30 days) and for this reason more wound closures can be achieved in the maximum treatment period of 42 days compared to the control therapy. Furthermore it is supposed that the application of NPWT represents an effective und save therapy option for the treatment of postoperative subcutaneous abdominal wound-healing impairments in inpatient and outpatient settings.**

**Patients will be randomized in a 1:1 ratio to the therapy arm NPWT and the control arm SCWT. The sample size estimation revealed that a maximum of 228 patients (Intention-To-Treat-analysis) has to be enrolled during the active recruitment period to achieve the sample size of 198 participants (Per-Protocol-analysis) necessary for statistical analysis.**

**Data acquisitions in the context of the evaluation of the primary endpoints and the secondary endpoints in the health economic, patient-related and safety-relevant context will generate reliable data fort he evaluation of efficacy and efficiency of NPWT in the therapy of postoperative abdominal wound-healing impairments in inpatient and outpatient settings. The results analyzed during the study conduct shall be provided until June 2014 to supply a contribution to the final decision of the Gemeinsamer Bundesausschuss (Federal Joint Committee) concerning a possible admission of negative pressure wound closure as a standard service of the statutory health insurance within both medical settings.**

## Organizational Data

- DRKS-ID: **DRKS00003498**
- Date of Registration in DRKS: **2012/01/27**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **115/2011 , Ethik-Kommission der Universität Witten/Herdecke**

## Secondary IDs

## Health condition or Problem studied

- Free text: **Iatrogenic subcutaneous abdominal wound healing disorder**
- ICD10: **S31.1 - Open wound of abdominal wall**
- ICD10: **T89.03 - [---]***

## Interventions/Observational Groups

- Arm 1: **Intervention group: Negative Pressure Wound Therapy (NPWT)**
- Arm 2: **Control group: Standard Conventional Wound Therapy (SCWT). Methods of simple and advanced wound treatment according to the therapy recommendations.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Controlled testing of two primary endpoints:**
**1) Time (number of days) to the achievement of complete wound closure (Time-to-Closure) within 42 days of treatment**

**2) Number of achieved wound closures within maximum therapy period (Rate-of-Closure) within 42 days of treatment**

**Secondary Outcome**

**Secondary endpoints related to efficacy:**

**•Reduction of wound volume in the course of treatment (over time)**

**•Wound infections**

**•Relapses**

**•Pain**

**•Quality of Live**

**Safety endpoints:**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- Medical Center **Städtisches Klinikum Karlsruhe, Karlsruhe**
- Medical Center **Städtisches Klinikum, Neunkirchen**
- Medical Center **Krankenhaus Martha Maria, Halle/Dölau**
- University Medical Center **Frankfurt a.M.**
- Medical Center **Asklepios Stadtklinik, Bad Tölz**
- Medical Center **Ortenau Klinikum Offenburg, Offenburg**
- Medical Center **Asklepios Westklinikum Hamburg, Hamburg**
- Medical Center **Klinikum Dorothea Christiane Erxleben, Quedlinburg**
- Medical Center **Asklepios Klinikum Uckermark GmbH, Schwedt**
- Medical Center **Dr. Horst Schmidt Kliniken GmbH, Wiesbaden**
- Medical Center **Krankenhaus St. Elisabeth, Halle Saale**
- Medical Center **Klinikum Darmstadt, Darmstadt**
- Medical Center **Kliniken der Stadt Köln, Köln**
- Medical Center **Gemeinschaftskrankenhaus Herdecke, Herdecke**
- University Medical Center **Universitätsklinikum Schleswig-Holstein, Lübeck**
- Medical Center **Evangelisches Krankenhaus Paul Gerhard Stift, Wittenberg**

- Medical Center **Sana Hanse-Klinikum Wismar GmbH, Wismar**
- Medical Center **Kreiskrankenhaus Blaubeuren, Blaubeuren**
- Medical Center **Westklinikum Heide, Heide / Holstein**
- Medical Center **Alexianer Krankenhaus Krefeld GmbH, Krefeld**
- Medical Center **Diakonissenkrankenhaus Dessau, Dessau**
- Medical Center **Klinikum Bielefeld, Bielefeld**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/07/15**
- Target Sample Size: **251**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **85 Years**

### Additional Inclusion Criteria

**Key inclusion criteria:**

**•Acute subcutaneous abdominal wound-healing impairment after surgical**

### Exclusion criteria

**Key exclusion criteria:**

**•Lack of infrastructure for outpatient continuation of treatment and study-specific interventions**

**•Existence of an open abdominal fascia**

## Addresses

- **Primary Sponsor**

  **Private Universität Witten/Herdecke gGmbH**
  **Mr. Dr. med. Marcus Redaèlli**
  **Alfred-Herrhausen-Str. 50**
  **58448 Witten**
  **Germany**

  Telephone: **+49 2302 926-741**
  Fax: **+49 2302 926-745**
  E-mail: **marcus.redaelli(at)uni-wh.de**
  URL: **www.uni-wh.de**

- **Contact for Scientific Queries**

  **Private Universität Witten/Herdecke gGmbH**
  **Mr. Dr. med. Marcus Redaèlli**
  **Alfred-Herrhausen-Str. 50**
  **58448 Witten**
  **Germany**

  Telephone: **+49 2302 926-741**
  Fax: **+49 2302 926-745**
  E-mail: **marcus.redaelli(at)uni-wh.de**
  URL: **www.uni-wh.de**

## Sources of Monetary or Material Support

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

  **AOK-Bundesverband GbR, Ersatzkassen: Barmer GEK, Techniker Krankenkasse (TK), Deutsche Angestellten-Krankenkasse, KKH_Allianz, HEK - Hanseatische Krankenkasse, hkk, Knappschaft; Kinetic Concepts Incorporated (KCI) & Smith&Nephew**
  **Germany**

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

## Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- 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.*