ISRCTN44577192 https://doi.org/10.1186/ISRCTN44577192

# Treatment of Iatrogenic Subcutaneous Abdominal Wounds (ISAW) after surgery

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 06/02/2012 | Stopped | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 04/04/2012 | Stopped | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 04/08/2016 | Injury, Occupational Diseases, Poisoning | [ ] Record updated in last year |

**Plain English summary of protocol**

Background and study aims
Open wounds are a major burden for the patient and lead to high healthcare costs. The aim of this study is to compare Negative Pressure Wound Therapy (NPWT) and standard wound therapy for the treatment of open abdominal wounds. NPWT involves using a sealed wound dressing connected to a vacuum pump to promote healing. We want to find out whether NPWT decreases the time it takes for the wound to close.

Who can participate?
Patients aged 18 to 85 with open abdominal wounds after surgery

What does the study involve?
Participants are randomly allocated into the intervention or control group. In the intervention group participants are treated with NPWT until wound closure, at most for 42 days. The control group receives standard wound therapy also for 42 days. After this the participants can be treated like before or with a different treatment. The following outcomes are measured: time taken for complete wound closure, number of wound closures within the 42 days of treatment, reduction of wound volume, wound infections, relapses, pain, quality of life and costs.

What are the possible benefits and risks of participating?
There are no additional risks for participants

Where is the study run from?
The study takes place country-wide at various clinical surgical departments in Germany, with a total of 25 departments/centres participating

When is the study starting and how long is it expected to run for?
February 2012 to November 2013

Who is funding the study?
Statutory Health Insurance (SHI) Germany

Who is the main contact?
Dr Tilman Treptau

# Contact information

### Type(s)
Scientific

### Contact name
Dr Tilman Treptau

### Contact details
Institute for Research in Operative Medicine
University Witten/Herdecke
Ostmerheimer Straße 200 (Haus 38)
Cologne
Germany
51109

# Additional identifiers

### Protocol serial number
DRKS ID 00003498

# Study information

### Scientific 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

### Acronym
ISAW

### Study objectives
1. 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.
2. 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.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)

University Witten/Herdecke Ethics Committee, 27/09/2011, ref: 115/2011

## Study design
Multicentre randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Iatrogenic Subcutaneous Abdominal Wounds

## Interventions
Intervention group: Negative Pressure Wound Therapy (NPWT)

Control group: Standard Conventional Wound Therapy (SCWT). Methods of simple and advanced wound treatment according to the therapy recommendations.

All participants are recruited consecutively and are randomised with a computer-assisted randomisation-list. The intervention group will be treated with VAC-therapy until wound closure, at maximum for 42 days. During the time of therapy every third day changing dressing is done.

The control group will be treated and observed according to the German Association of Wound Healing and Wound Treatment also within 42 days (maximum). After the maximal duration of study treatment the participants can be treated like before or with alternative therapy. The participants of both groups will be seen after 180 days within the follow-up.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
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

## Key secondary outcome(s))
1. Reduction of wound volume in the course of treatment (over time)
2. Wound infections
3. Relapses
4. Pain
5. Quality of Live
6. Patient-related endpoints / Patient Reported Outcome (PRO)
7. Consumption of resources in inpatient and outpatient setting and costs (economically orientated outcome parameters)
8. Stratification according to wound volume and study centre

### Completion date
30/11/2013

### Reason abandoned (if study stopped)
Participant recruitment issue

## Eligibility

### Key inclusion criteria
1. Acute subcutaneous abdominal wound-healing impairment after surgical intervention
2. Sizes of wound opening (maximum diameter ≥ 3 cm)
3. Wound depth ≥ 3 cm
4. Wound surface ≥ 9 cm2

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Lack of infrastructure for outpatient continuation of treatment and study-specific interventions
2. Existence of an open abdominal fascia
3. Acute serious organ failure
4. Application of an other active vacuum device at the wound treated during the study conduct within 8 days before screening visit
5. Ongoing/during 3 weeks after chemo therapy
6. Ongoing/during 3 weeks after radiation therapy
7. Contraindications in accordance with the safety precautions issued by the FDA or the companies

### Date of first enrolment
15/02/2012

### Date of final enrolment
30/11/2013

## Locations

### Countries of recruitment
Germany

**Study participating centre**
**University Witten/Herdecke**
Cologne
Germany
51109

# Sponsor information

**Organisation**
University Witten/Herdecke (Germany)

**ROR**
https://ror.org/00yq55g44

# Funder(s)

**Funder type**
Government

**Funder Name**
General Insurance Fund [Allgemeine Ortskrankenkassen] (Germany)

**Funder Name**
Health Insurance Association [Verband der Ersatzkassen] (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? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |