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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

Study website
http://www.wound-care.de/ (in German)

Contact information

Type(s)
Scientific

Contact name
Dr Tilman Treptau

Contact details
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51109

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
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 measures
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

Overall study start date
15/02/2012

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

Age group
Adult

Sex
Both

Target number of participants
250

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)

Sponsor details
c/o Prof. h.c. Edmund A. M. Neugebauer
Chair for Surgical Research
The Institute for Research in Operative Medicine
Faculty of Health, Department of Medicine
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51109

Sponsor type
University/education

Website
http://www.uni-wh.de/

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

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