ISRCTN31224450 https://doi.org/10.1186/ISRCTN31224450

# Negative pressure therapy in large incisional hernia surgery

**Submission date**
26/03/2013

**Recruitment status**
Stopped

**Registration date**
30/04/2013

**Overall study status**
Stopped

**Last Edited**
28/08/2018

**Condition category**
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Incisional hernia is a common and debilitating complication of abdominal surgery, with a reported incidence of between 10 and 25% of laparotomies. There is no consensus regarding the best surgical technique to treat this condition although the use of prosthesis is recommended in cases involving large hernias.
Relapse rates of 5 to 63% have been documented in patients who have undergone incisional hernia surgery, and other serious complications such as seromas, hematomas and wound infections have also been described. The development of seromas relates to fluid accumulation in the residual space of the hernia along with inflammation, disruption of lymphatics and continuous irritative effect caused by the foreign body like the prosthesis. For the prevention of postoperative seromas suction drains are placed in the subcutaneous dissection space allowing aspiration of fluid produced, along with measures of elastic compression postoperatively.
Since 1997 it has been described the use of negative pressure therapy to treat complex and open wounds. Over the years the advantages of the technique have been demonstrated, as it improves healing times by increasing blood flow, extracting secreted fluid, maintaining the wound margins and protecting the wound from contamination.
Negative pressure therapy was also later used for the treatment of closed wounds. The Prevena Incision Management System® (Kinetic Concepts Inc, San Antonio, TX, USA), which has recently appeared on the market, is specifically designed for the treatment of closed wounds and has proven effective in preventing seromas and hematomas in sternotomic and traumatologic wounds.
The Prevena Incision Management System® consists of a sponge dressing on an adhesive sheet with a suction drain with a small tank for collecting fluids. When the system is applied it holds the wound in place, isolates it from the exterior, and extracts fluids form the wound by applying negative pressure of 125 mmHg.
One study applying a conventional VAC (Vacuum Assisted Clossure) dressing as the postoperative treatment of three hernioplasties, advances the possible protective effect of negative pressure therapy in the appearance of postoperative seromas after hernioplasty. The same results were observed using the specific Prevena ® dressing in pork abdominal wounds. In our department we performed a pilot study applying negative pressure therapy by Prevena ® device to 5 patients undergoing large incisional hernia, with no postoperative complications and statistically significant reduction in postoperative drainage time required compared to a control

group traditional dressing.
The objectives of this study are to assess the effectiveness of the negative pressure therapy applied on the wound of large incisional hernia surgery reducing time and subcutaneous drain debit and also in reducing postoperative complications and recurrence. Another objective is an economic analysis of the use of negative pressure therapy in these wounds.

Who can participate?
Study participants were patients from the University Hospital of Tarragona Joan XXIII who underwent elective surgery for incisional hernia with diameters exceeding 10 cm.

What does the study involve?
Patients who met the inclusion criteria, which are scheduled for incisional hernia repair of larger than 10 cm in diameter, were randomly distributed into two groups (control and NPT)
Patients in the control group were applied in the conventional postoperative compression dressing.
Patients in the NPT group, the device Prevena Incision Management System ® was immediately applied to the closed wound in the operating theatre. The dressing was left in place for seven days.
We recorded all postoperative complications, how long the drains were left in place, and any adverse reactions to the dressing. Abdominal CT scans were performed to confirm the presence or absence of post-operative seromas.

What are the possible benefits and risks of participating?
The expected benefits are decreasing the amount of drainage from the wound, reduced drainage time and hospital stay, and decreased postoperative seromas
No adverse effects have been reported from the use of negative pressure therapy in closed wounds.

Where is the study run from?
The study was conducted in the General and Digestive Surgery Department, University Hospital Joan XXIII in Tarragona, Spain

When is the study starting and how long is it expected to run for?
The study started in February 2013 and is expected to run for 12 months.

Who is funding the study?
General Surgery Department of University Hospital Joan XXIII (Spain) and Kinetic Concepts Inc, San Antonio, TX (USA) is providing the material.

Who is the main contact?
Dr Carles Olona
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Carles Olona

**Contact details**
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43007

# Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
HJ23-C.1-N-12

# Study information

**Scientific Title**
Negative pressure therapy in large incisional hernia surgery: a postoperative prospective randomised controlled study

**Study objectives**
The negative pressure therapy applied on the wound of large incisional hernia surgery reduces time and subcutaneous drain debit and also reduces postoperative complications and recurrence.

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
The study is approved by the Scientific Committee of Clinical Research of the University Hospital Joan XXIII of Tarragona (Spain) on 04/03/2013, ref: CEIC 03/2013.

**Study design**
Longitudinal prospective randomised controlled case-control single centre study

**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
Seroma, volume and time drainage, and complications in large incisional hernia postoperative

### Interventions
Patients in the control group were applied in the conventional postoperative compression dressing.

Patients in the Negative Pressure Therapy group, the device Prevena Incision Management System ® was immediately applied to the closed wound in the operating theatre. The dressing was left in place for seven days.

### Intervention Type
Procedure/Surgery

### Phase
Not Applicable

### Primary outcome measure
The measures will be the volume accumulated in the drains every 24 hours in ml, and the number of days necessary to reduces this volume under 50ml/24h

### Secondary outcome measures
1. Postoperative complications appeared as seromas, hematomas, wound infection and relapse
2. Cost analysis including the length of stay and the number o dressings changes

### Overall study start date
01/02/2013

### Completion date
01/02/2014

### Reason abandoned (if study stopped)
Lack of funding/sponsorship

## Eligibility

### Key inclusion criteria
1. Patients operated on large incisional hernia in the Joan XXIII Hospital Surgery Department
2. Patients over 18 years
3. With incisional ring diameter over 10 cm
4. American Society of Anesthesiologists (ASA) lower than 4
5. Operated with Chevrel technique

### Participant type(s)
Patient

### Age group

Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
The target total recruitment is 26 participants for the trial, 13 for arm

### Key exclusion criteria
1. ASA grade 4
2. Patients with wound infections before surgery
3. Previous eventroplasty
4. Pregnant
5. Surgical intervention using another technique than Chevrel eventroplasty

### Date of first enrolment
01/02/2013

### Date of final enrolment
01/02/2014

## Locations

### Countries of recruitment
Spain

### Study participating centre
**Merce Rodoreda 11-B 2º 1ª**
Tarragona
Spain
43007

## Sponsor information

### Organisation
University Hospital Joan XXIII de Tarragona (Spain)

### Sponsor details
Dr. Mallafré Guasch 4
General and Digestive Surgery Department

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43005

**Sponsor type**
Government

**ROR**
https://ror.org/05s4b1t72

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
General Surgery Department of University Hospital Joan XXIII (Spain)

**Funder Name**
Kinetic Concepts Inc, San Antonio, TX (USA) - providing the material

# 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