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Novel method for delayed primary closure and incisional hernia prevention in open abdomen

Submission date 21/10/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 13/12/2016	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 11/04/2019	**Condition category** Surgery	[_] Individual participant data

Plain English summary of protocol

Background and study aims
The term open abdomen refers to when an incision (cut) in the abdomen is intentionally left open at the end of surgery. It is a treatment option for cases of trauma (injury) but also for non-trauma patients, especially for those with severe sepsis (blood poisoning). Various techniques of temporary abdominal closure have been developed in order to achieve closure with few complications such as incisional hernia. The aim of this study is to test whether a new method called COmbined and MOdified Definitive Abdominal closure (COMODA), which involves applying low pressure combined with a fixed mesh, increases the rate of closure and reduces the risk of developing an incisional hernia.

Who can participate?
Patients aged 18 - 80 with an open abdomen that is not due to trauma

What does the study involve?
The patients' wounds are examined every 3-4 days or on demand to measure the rate of closure. The incidence of incisional hernia is measured by CT scan after 6 months.

What are the possible benefits and risks of participating?
The treatment may increase the rate of closure and decrease the risk of developing an incisional hernia. There are risks of surgical complications (bowel adhesions, enteroatmospheric fistulae).

Where is the study run from?
Arnau de Vilanova University Hospital (Spain)

When is the study starting and how long is it expected to run for?
January 2015 to June 2016

Who is funding the study?
1. B. Braun Surgical
2. Smith & Nephew

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CEIC 1663

Study information

Scientific Title
COMODA method: combined and modified definitive abdominal closure method

Study objectives
Open abdomen management has become a therapeutic option for not only cases of trauma but also for non-trauma patients, especially for those with severe sepsis. It is nonetheless associated with high rates of morbidity and mortality. Various techniques of temporary abdominal closure have been developed in order to improve the management and to achieve delayed primary closure with minimal complications, either early or late (incisional hernia). A novel method called COmbined and MOdified Definitive Abdominal closure (COMODA) has been developed for obtaining a delayed open abdomen primary closure with a lower risk for subsequently developing an incisional hernia.

This observational study is taking place to find out whether use of COMODA can improve abdominal wall closure in open abdomen and avoid a posterior incisional hernia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
CEIC (Comité Ético de Investigación Clínica), Clinical Research Ethics Committee, 04/10/2016, ref: CEIC-1663

Study design
Observational prospective study in a single center

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Critical non-trauma patient with an open abdomen

Interventions
Prospective observational study in which a negative pressure wound therapy (NPWT) system is combined with a condensed polytetrafluoroethylene (cPTFE) mesh fixed 5 cm from the aponeurotic edges. Demographic variables, comorbidities, intra-abdominal pressure measurements, number of surgeries, time until definitive closure, early and late complications were studied. This method was used in non-trauma patients, mainly with sepsis, with the wound being examined every 3-4 days or on demand, with constant medial traction applied to the edges. When primary closure was achieved, the remaining cPTFE mesh served as intraperitoneal reinforcement. The treatment is a new technique for abdominal wall closure in open abdomen that the authors hope will allow closure in 2 - 3 weeks. Follow-up after closure: 6 months.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure

Rate of definitive abdominal wall closure, determined by wound examination every 3-4 days until closure

Secondary outcome measures
Incidence of incisional hernias, determined with abdominal computerized tomography after 6 months

Overall study start date
15/01/2015

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Non-trauma critical patient with open abdomen
2. Age range: 18 - 80

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Total final enrolment
10

Key exclusion criteria
Trauma critical patients with open abdomen

Date of first enrolment
01/02/2015

Date of final enrolment
30/03/2016

Locations

Countries of recruitment

Spain

Study participating centre
Arnau de Vilanova University Hospital
Lleida
Spain
25006

Sponsor information

Organisation
Arnau de Vilanova University Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01p3tpn79

Funder(s)

Funder type
Industry

Funder Name
B. Braun Surgical

Funder Name
Smith & Nephew

Results and Publications

Publication and dissemination plan
This study will be published in an open access journal.

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		12/12/2016	27/01/2017	No	No
Results article	results	01/04/2020	11/04/2019	Yes	No