

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

Submission date 21/10/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/12/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/04/2019	Condition category Surgery	<input type="checkbox"/> 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

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

ROR

<https://ror.org/01p3tpn79>

Funder(s)

Funder type

Industry

Funder Name

B. Braun Surgical

Funder Name

Smith & Nephew

Results and Publications

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?
Results article	results	01/04/2020	11/04/2019	Yes	No
Basic results		12/12/2016	27/01/2017	No	No