

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Slowly-absorbable mesh versus standard care in the management of contaminated mid-line incisional hernia (COMpACT-BIO): A multicenter randomized controlled phase III trial including a health economic evaluation.
AUTHORS	Passot, G; Margier, Jennifer; Kefleyesus, Amanuel; Rousset, Pascal; Ortega-Deballon, Pablo; renard, yohann; Bin, Sylvie; VILLENEUVE, LAURENT

VERSION 1 – REVIEW

REVIEWER	Kudsi, Omar Tufts University School of Medicine
REVIEW RETURNED	22-Feb-2022

GENERAL COMMENTS	<p>This is a very good protocol for an interesting subject, especially the cost aspect. No particular comments in general, just some grammar errors to address.</p> <p>Page 2 : adjust affiliation capitalization Page 5 line 12: remove “of” “...current standard treatments...” Page 8 line 40: “...resist infections. However, they were absorbed within...” Page 9 line 18: reword to “The COMpACT-BIO study compares the placementprocedures for mid-lines His...modified VHWG (primary...surgeon).” Page 13 line 53: “The COBRA study reported a clinical recurrence... with the use of...environment.” Page 18 line 38: “QALYs are a composite measure which combines...” Page 19 line 5: “A sensitivity analysis...” Page 20 line 56: “The investigator is not proceeding with any..”</p>
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REVIEWER	Kojima, Koichiro Kyorin University School of Medicine, Surgery
REVIEW RETURNED	01-Mar-2022

GENERAL COMMENTS	<p>1)Page9 Line29 At what point during the surgery did the randomization occur and who made the decision?</p> <p>2)Page10 Line3-43 Please describe in detail the surgical technique for mesh placement, including whether the hernia portals were sutured, how much the mesh was overlapped from the hernia portals, and the method of mesh fixation.</p>
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	<p>3)Page11 Line28 How to diagnose infectious complications? Who diagnosed it?</p> <p>4)Page14 Line43 What is the definition of surgical failure?</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Page 2 : adjust affiliation capitalization
We made the changes.

Page 5 line 12: remove “of” “...current standard treatments...”
We made the changes.

Page 8 line 40: “...resist infections. However, they were absorbed within...”
We made the changes.

Page 9 line 18: reword to “The COMpACT-BIO study compares the placementprocedures for mid-lines His...modified VHWG (primary...surgeon).”
We made the changes.

Page 13 line 53: “The COBRA study reported a clinical recurrence... with the use of...environment.”
We made the changes.

Page 18 line 38: “QALYs are a composite measure which combines...”
We made the changes.

Page 19 line 5: “A sensitivity analysis...”
We made the changes.

Page 20 line 56: “The investigator is not proceeding with any..”
We made the changes.

Reviewer: 2

1)Page9 Line29
At what point during the surgery did the randomization occur and who made the decision?
The randomization was performed during surgery before closure. We made the following changes:
Randomization is done during surgery before closure the fascia with an allocation ratio of 1:1.

2)Page10 Line3-43
Please describe in detail the surgical technique for mesh placement, including whether the hernia portals were sutured, how much the mesh was overlapped from the hernia portals, and the method of mesh fixation.

We made the following changes:

The main steps of the surgical technique were:

- Complete resection of the sac
- Retro rectus dissection preserving neurovascular bundles
- Posterior fascia closure using small bites technique with slowly resorbable tread
- Mesh placement in retrorectus position with a 5 cm overlap
- Mesh fixation using slowly resorbable tread
- Anterior fascia closure using small bites technique with slowly resorbable tread

3)Page11 Line28

How to diagnose infectious complications? Who diagnosed it?

We made the following changes, and defined how complication diagnosis were made.

Infectious complications were defined by all fluid collection in the surgical field, either associated with general sepsis sign or not. When feasible, fluid collection would be ponctionned for bacteriological assessment. All parietal complications would be confirmed by a CTscan.

4)Page14 Line43

What is the definition of surgical failure?

We would considere a surgical failure, all surgery were the standard technique could not be performed as defined in the protocol (component separation required, no posterior fascia for any raison making the retrorectus mesh placement non feasible...) all deviation to the standard technique will be considered as a surgical failure. We made the following changes to better define this point.

- Failure to carry out the surgery as defined in the protocol;

VERSION 2 – REVIEW

REVIEWER	Kudsi, Omar Tufts University School of Medicine
REVIEW RETURNED	17-May-2022

GENERAL COMMENTS	Thank you for answering both reviewers feedback
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REVIEWER	Kojima, Koichiro Kyorin University School of Medicine, Surgery
REVIEW RETURNED	22-May-2022

GENERAL COMMENTS	<p>The paper has improved very well and is almost ready to be accepted. However, I would like to request a few additions regarding the secondary endpoints.</p> <p>Page12 line35-36 7.The delay between surgery and the end of care for the mid line scar (following initial IH surgical repair)</p> <p>How is the end of care for the mid line scar defined ?</p>
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VERSION 2 – AUTHOR RESPONSE

Thank you for your interest in our study.

Regarding reviewer 2 comment, we defined the end of care, as the day of the last dressing.

We change the manuscript accordingly.

VERSION 3 – REVIEW

REVIEWER	Kojima, Koichiro Kyorin University School of Medicine, Surgery
REVIEW RETURNED	20-Jun-2022
GENERAL COMMENTS	Thank you for the detailed corrections. No further corrections are desired.

VERSION 3 – AUTHOR RESPONSE

Reviewer: 2

Dr. Koichiro Kojima, Kyorin University School of Medicine Comments to the Author:

Thank you for the detailed corrections. No further corrections are desired.