

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

Title (Provisional)

Obsidian ASG Autologous Platelet-Rich Fibrin Matrix for the prevention of postoperative pancreatic fistula following pancreatic resection: Study protocol for a feasibility trial at the Medical University of Vienna

Authors

Gustorff, Charlotte; Dawoud, Christopher; Leonhardt, Carl-Stephan; Riss, Stefan; Sahara, Klaus; Schindl, Martin; Strobel, O.; Klaiber, Ulla

VERSION 1 - REVIEW

Reviewer	1
Name	Smits, F Jasmijn
Affiliation	UMC Utrecht
Date	13-Aug-2024
COI	none

With great interest i have read the trial proposal. As this remains a topic that is of interest and there is not yet a definitive awnser to the efficacy of sealants in prevention of pancreatic fistula. I have only a few minor comments / questions.

1. There is a typo in abstract (204 should be 2024 i think)
no details on type of matching procedure (propensity score matching or any other method?)
2. What I am missing is the descripton of matching procedure, will you use propensity score matching or just 1:1 matching based on the characteristics mentioned? Please explain why this method is used.
3. What type of adversed events are expected, in other words, why would you expect to need a safety study if this procedure is already being used in other but comparable types of resections?
4. Please add the definition on your primary endpoint, i.e. what you find a successful trial intervention.

Reviewer	2
Name	Tafti, Seyed Mohsen Ahmadi
Affiliation	Tehran University of Medical Sciences

Date 27-Aug-2024
COI No conflict of interest

The questionnaire seems to be OK, it would have been nice to have read the detailed technique of surgery as well. But the material are adequate.

VERSION 1 - AUTHOR RESPONSE

Reviewer: 1

Dr. F Jasmijn Smits, UMC Utrecht

Comments to the Author:

With great interest i have read the trial proposal. As this remains a topic that is of interest and there is not yet a definitive awnser to the efficacy of sealants in prevention of pancreatic fistula. I have only a few minor comments / questions.

**1. There is a typo in abstract (204 should be 2024 i think)
no details on type of matching procedure (propensity score matching or any other method?)**

Thank you for hint. The typo was corrected.

2. What I am missing is the description of matching procedure, will you use propensity score matching or just 1:1 matching based on the characteristics mentioned? Please explain why this method is used.

There will be a 1:2 matching with patients from a historic collective on the basis of their characteristics (age, procedures and histopathological findings) in order to receive t_Wo comparable study groups.

3. What type of adversed events are expected, in other words, why would you expect to need a safety study if this procedure is already being used in other but comparable types of resections?

Given the chance of these resections to result in pancreatic fistulas and the occurrence of severe surgical complications, the introduction of a new application of the medicinal product may potentially give rise to unforeseen issues like postoperative infection or a prolongation of operative time. However, we are confident that this is an unlikely scenario, given the proven safety of Obsidian in colorectal surgery.

Secondly, the objective of this study is to gain experience in the standard operating procedures in applying Obsidian in pancreatic resections, with a view to applying this kno_Wledge in future investigations.

4. Please add the definition on your primary endpoint, i.e. what you find a successful trial intervention.

As successful trial intervention the successful application of Obsidian intraoperatively to the pancreatic anastomosis or pancreatic stump will be counted. This information was added to the Outcome parameters section.

Reviewer: 2

Dr. Seyed Mohsen Ahmadi Tafti, Tehran University of Medical Sciences

Comments to the Author:

The questionnaire seems to be OK, it would have been nice to have read the detailed technique of surgery as well.

But the material are adequate.

Thank you for your kind remarks. We added details concerning the used technique of surgery: Distal pancreatectomy is usually performed open using an arterial or uncinate first approach and including the TRIANGLE procedure in patients with cancer. Also, to be added a frozen section specimen will standardly be taken from the pancreatic and bile duct remnant.