## PEER REVIEW HISTORY



## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | Nasogastric/Nasoenteric tube-related incidents in hospitalized patients: a study protocol of a multicenter prospective cohort study |
| **AUTHORS** | Gimenes, Fernanda; Pereira, Marta; Prado, Patricia; Carvalho, Rhanna; Koepp, Janine; Freitas, Ligia; Teixeira, Thalyta; Miasso, Adriana |

## VERSION 1 – REVIEW

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| **REVIEWER** | Mahdi Najafi<br>Tehran Heart Center<br>Tehran University of Medical Sciences<br>Iran |
| **REVIEW RETURNED** | 21-Jan-2019 |

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| **GENERAL COMMENTS** | I reviewed the research protocol entitled "Feeding tube-related incidents in hospitalized patients: a study protocol of a prospective study." by Gimenes and colleagues with interest. This group of researchers are aimed at evaluating the incidence and the impact of nasogastric tube complications. Its multi enter design as well as their comprehensive approach to every element of the study are among positive points of this protocol. They have decided to employ measures normally used by nursing to verify the patients' conditions such as PCS which is another strength of this proposal. However, I would use another well-known scoring system for critically ill patients to pave the way for future comparison of data with other centers and have publications with robust methods.<br>The other aspect that should not be overlooked is the level of consciousness. Though the researchers have included measures for assessment of general condition and severity of illness, it doesn't preclude the need for a measure such as Glasgow Coma Scale (GCS). Besides, Checking if reflexes such as gag are intact is important as well. The other item that everyone probably is interested to know is time to insertion of NGT and who performs.<br>I'd like to emphasize on another pivotal point in this protocol that needs more clarification. They want to study enteral feeding tube. However, it is not well defined so that in subject section they make no difference between feeding tube and NGT "The inclusion criteria are: patients older than 18 years; who are admitted to the medical ward with a nasogastric or a nasoenteric feeding tube (or patients who require the insertion of a nasogastric or nasoenteric feeding tube during hospitalization)". They should distinguish between these two if they think it is necessary then explain how they make sure the enteral tube is in site. If these are not really important (that is not probably the case) they should omit the misleading term enteral feeding tube and make it clear whether or not they include patients who need NGT for drainage of gastric content. |

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| | With regard to complications I would omit metabolic incidents at it is a quite difficult if possible at all to differentiate feeding tube related complications from the others.<br>There are minor errors that are correctable by reading through the text another time such as noting 8 centers instead of 7 somewhere in manuscript and some other really minor typos.<br>I hope these comments help the researchers improve the design and descriptions and prapare a promising project protocol to fulfill their research goals and expectations. |

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| **REVIEWER** | Keith Miller<br>University of Louisville |
| **REVIEW RETURNED** | 29-Jan-2019 |

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| **GENERAL COMMENTS** | The authors are to be commended on the development of a prospective evaluation of the morbidity, and potential mortality, of enteral access procedures in the hospital setting. This is certainly a common intervention in the hospital and the majority of the existing data is retrospective in nature. Clinical practice is generally dictated by local and regional dogma, as described. Strengths of this study include the multi-institutional nature and the objective involving close examination of the medications given by tube and potential resultant issues. I do believe that this study has the potential to result in findings that could alter current practices, or at the least better define the morbidity associated with current practice. I see no ethical issues with the study design and look forward to the results. |

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| **REVIEWER** | Laurent Genser<br>Sorbonne Université<br>Pitié Salpetriere University Hopsital<br>Paris, France |
| **REVIEW RETURNED** | 23-Apr-2019 |

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| **GENERAL COMMENTS** | The authors have to be congratulated for this study project. Indeed only few large scale studies described the specific tube related morbi mortality and therefore could help to reduce the healthcare costs and improve patients carepathway especialy in oncologic settings.<br>I have only two questions:<br>-Regarding data collection, is survey monkey allowed for anonymous medical data collection?<br>-Why do you limit your study to the hospital stay period since enteral nutrition is often initiated on the initial hospital stay and continued (for a longer period) at home until malnutrition correction or to prepare patients to surgical procedure? |

## VERSION 1 – AUTHOR RESPONSE

| Reviewer' Comments (1) | Authors' Response |
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| I would use another well-known scoring system for critically ill patients to pave the way for future comparison of data with other | Thank you for this advise. However, in this study, we will not include patients from intensive care units and many well-known scoring systems include clinical indicators that are not assessed in |

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| centers and have publications with robust methods. | the routine fashion in ward patients. For this reason, we decided to use the PCS proposed by Fugulin, which is the most used method to evaluate patient complexity in hospital wards. |
| The other aspect that should not be overlooked is the level of consciousness. Though the researchers have included measures for assessment of general condition and severity of illness, it doesn't preclude the need for a measure such as Glasgow Coma Scale (GCS). Besides, Checking if reflexes such as gag are intact is important as well. | Thank you for your advise. We included the assessment of patients' level of consciousness measured by GCS (page 9) in our study protocol. |
| The other item that everyone probably is interested to know is time to insertion of NGT and who performs. | Thank you for your comment. We included a sentence about who performs NGT (page 10) and time to insertion (page 9). |
| I'd like to emphasize on another pivotal point in this protocol that needs more clarification. They want to study enteral feeding tube. However, it is not well defined so that in subject section they make no difference between feeding tube and NGT "The inclusion criteria are: patients older than 18 years; who are admitted to the medical ward with a nasogastric or a nasoenteric feeding tube (or patients who require the insertion of a nasogastric or nasoenteric feeding tube during hospitalization)". They should distinguish between these two if they think it is necessary then explain how they make sure the enteral tube is in site. If these are not really important (that is not probably the case) they should omit the misleading term enteral feeding tube and make it clear whether or not they include patients who need NGT for drainage of gastric content. | We included a definition of a short-term feeding tube (page 4) and revised the inclusion criteria proposed for this study. We specified that only patients with a nasally placed feeding tube or a nasally placed small-bowel feeding tube will be included (page 7). |
| With regard to complications I would omit metabolic incidents at it is a quite difficult if possible at all to differentiate feeding tube related complications from the others. | Thank you for your advise. We excluded this variable from our study protocol. |
| There are minor errors that are correctable by reading through the text another time such as noting 8 centers instead of 7 somewhere in manuscript and some other really minor typos. | Thank you for your comment. The entire paper was reviewed and corrections were made. |

| Reviewer' Comments (2) | Authors' Response |
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| The authors are to be commended on the development of a prospective evaluation of the morbidity, and potential mortality, of enteral access procedures in the hospital setting. This is certainly a common intervention in the hospital and the majority of | Thank you very much for you comments. We believe the results will contribute to changes in practice. |

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| the existing data is retrospective in nature. Clinical practice is generally dictated by local and regional dogma, as described. Strengths of this study include the multi-institutional nature and the objective involving close examination of the medications given by tube and potential resultant issues. I do believe that this study has the potential to result in findings that could alter current practices, or at the least better define the morbidity associated with current practice. I see no ethical issues with the study design and look forward to the results. | |

| Reviewer' Comments (3) | Authors' Response |
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| The authors have to be congratulated for this study project. Indeed only few large scale studies described the specific tube related morbi mortality and therefore could help to reduce the healthcare costs and improve patients carepathway especialy in oncologic settings.<br>I have only two questions:<br>-Regarding data collection, is survey monkey allowed for anonymous medical data collection? | Access links to the data collection tools developed in the Survey Monkey platform will be provided to the research assistants. Thus, only the principal investigator and the sites coordinators will have access to the database.<br>In addition, for confidentiality purposes, each patient will be identified by a unique identification number, as mentioned in the methods section (page 10). |
| -Why do you limit your study to the hospital stay period since enteral nutrition is often initiated on the initial hospital stay and continued (for a longer period) at home until malnutrition correction or to prepare patients to surgical procedure? | Thank you very much for your comment. The study does not have funding, which makes it impossible to carry out a longitudinal study. However, this suggestion will be considerate in a future research. |

**VERSION 2 – REVIEW**

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| **REVIEWER** | Mahdi Najafi<br>Tehran Heart Center, Tehran University of Medical Sciences, Tehran, Iran.<br><br>Schulich School of Medicine & Dentistry, Western University, London, Canada. |
| **REVIEW RETURNED** | 18-May-2019 |

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| **GENERAL COMMENTS** | In my second review of the manuscript I feel to authors' aims and approach has been defined better and they have distinguished between some misleading terms. However, I'm still concerned about the term "feeding tube" rather than nasogastric tube" as I find the latter more appropriate with regards to their goals. I emphasize on keeping this in mind throughout their investigation not to overlook valuable resources that are matched with their own |

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| | project. For instance, they need any reference that discusses nasogastric tube including a recent comprehensive review (Sanaei et al Anaesthesiol Intensive Ther. 2017;49(1):57-65). Overall, I hope their endeavor will result in fruitful findings. |

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| **REVIEWER** | Laurent Genser<br>Service de Chirurgie Générale, Digestive et Cancérologique, Bariatrique et Métabolique<br>Hôpital Avicenne - Assistance Publique Hôpitaux de Paris<br>Hôpitaux Universitaires Paris Seine Saint Denis<br>125, rue de Stalingrad<br>93009 Bobigny Cedex |
| **REVIEW RETURNED** | 13-May-2019 |

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| **GENERAL COMMENTS** | all the comments addressed have been answered |

**VERSION 2 – AUTHOR RESPONSE**

| Reviewer' Comments (1) | Authors' Response |
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| In my second review of the manuscript I feel to authors' aims and approach has been defined better and they have distinguished between some misleading terms. However, I'm still concerned about the term "feeding tube" rather than nasogastric tube" as I find the latter more appropriate with regards to their goals. I emphasize on keeping this in mind throughout their investigation not to overlook valuable resources that are matched with their own project. For instance, they need any reference that discusses nasogastric tube including a recent comprehensive review (Sanaei et al Anaesthesiol Intensive Ther. 2017;49(1):57-65). Overall, I hope their endeavor will result in fruitful findings. | Thank you very much for your comments and for the reference provided which we accessed. We are now using the term NGT/NET for nasogastric tube and nasoenteric tube once we will include patients with an enteral access device with distal tip positioned in the stomach or small intestine. We are using the definitions provided by the American Society for Parenteral and Enteral Nutrition (ASPEN), because they are the same used by our National Society for Parenteral and Enteral Nutrition (BRASPEN). |