THESIS PROTOCOL

NASOJEJUNAL FEEDING VS. ORAL FEEDING FOLLOWING ENDOSCOPIC DRAINAGE OF WALLED OFF PANCREATIC NECROSIS: A RANDOMIZED CONTROLLED PILOT STUDY

PROTOCOL

Submitted in partial fulfilment of the requirement for the degree of DM

(Gastroenterology)

Post Graduate Institute of Medical Education and Research,

Chandigarh, India

June 2025

Dr SAURABH KUMAR SINGH

Patient information sheet

Protocol Number:

Name of the Participant:

Principal Investigator: Dr. Saurabh Kumar Singh

Name of the Institute: PGIMER, Chandigarh

Title - Nasojejunal feeding vs. oral feeding following endoscopic drainage of walled off pancreatic necrosis: a Randomized controlled pilot study

1. You are invited to take part in this research study. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.

2. What is the purpose of the study?

You are suffering from moderately severe or severe acute necrotising pancreatitis casuing fever and other complications. As you also have symptomatic walled off necrosis requring drianage, you are invited to participate in the study. Your management involves use of intravenous antibiotics and drainage of the collections. The optimal route of nutritional support following endoscopic drainage of walled-off pancreatic necrosis (WON) remains uncertain. While you may consider starting oral feeding once drainage is achieved, nasojejunal (NJ) feeding could offer more controlled and continuous nutrition, particularly if there is ongoing systemic inflammation or gastrointestinal intolerance. Currently, there is limited evidence directly comparing NJ feeding with oral feeding in this setting. Through this pilot randomized controlled study, we will assess whether nasojejunal feeding provides any clinical advantage over oral feeding in terms of recovery, complications, or the need for further interventions after endoscopic drainage of WON.

3. What is the expected duration for the completion of study?

The study duration will be till clinical success is achieved.

4. Do I have to take part in it?

It is up to you to decide whether or not to take part in it. If you do decide to be a part of the study, you will be given this written informed consent form to sign. In spite of being a part of it, you are still free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

5. What procedures will be followed during this study?

If you choose to be a part of the study, a written informed consent will be obtained from you. A detailed history and thorough physical examination will be undertaken. All available investigations will be noted. Your management of pancreatic WON will be done as per standard international guidelines, Institute's policy and per discretion of your treating physician. Once you are enrolled in the study, the decision to add nasojejunal feed or oral feed, beside metal stent placement, will be based on randomization.

6. What are the possible risks and discomforts of taking part in the study?

Your management will include usage of antibiotics, iv fluids, enteral or parenteral nutrition, endoscopic or percutaneous drainage as per the standard guidelines.Endoscopic transluminal drainage carry a risk of pain, bleeding, perforation, fistula formation, need for surgery, need

for transfusions and need for prolonged hospitalisation if any of the adverse events occur. However, the mentioned complications are associated with the standard of care management and no additional complications will be caused by taking part in the study.

7. What benefits are expected from this research?

It is hoped that the information obtained from this study will help determine the more effective route of nutritional support: nasojejunal feeding or oral feeding following endoscopic drainage of infected walled-off pancreatic necrosis (WON). If a clear benefit is demonstrated, the findings may contribute to the development of a standardized nutritional protocol, potentially reducing complications, lowering hospital costs, and improving overall patient outcomes

8. What will happen if I do not give consent?

You are free not to give consent regarding the participation in this study and this will not affect the treatment, management or follow up in PGIMER and you are free to withdraw from the study at any time you want. You will be given standard treatment of care as per the institutional protocol and necessary interventions will be carried out as and when needed.

9. Are the data/records of the participant kept confidential?

Yes. If you decide to take part in the study, your medical records will be directly inspected by the investigators taking care of you. Every precaution will be taken to respect the privacy & confidentiality of the patient. Some of the information collected about patients may be published in medical journals or presented in scientific conferences without disclosing patient's personal identity.

10. What are your responsibilities during participation in the study?

In event of any issue or problem that you face during the study, you must inform the investigators. You must follow the instructions that have been explained to you at the start of and during the study and any deviation from this should be informed to the investigators.

11. The Investigator may terminate the participant's participation without the participant's consent due to any circumstances whatsoever.

12. No additional costs will be borne by the participant from participation in the study.

13. Whom to contact for trial related queries?

The list of contacts has been provided below.

Contact persons:

For further information / questions, you can contact us at the following address:

Dr. Saurabh Kumar Singh

Senior Resident

Department of Gastroenterology, PGIMER, Chandigarh, India.

Tel: +91 8146615970

Prof. Surinder Singh Rana

Professor

Department. of Gastroenterology, PGIMER, Chandigarh, India.

Tel: +91 172 2756555

Informed consent sheet

Title: Nasojejunal feeding vs. oral feeding following endoscopic drainage of walled off pancreatic necrosis: a Randomized controlled pilot study

Name of the participant: …….

Name of the Principal Investigator: Dr. Saurabh Kumar Singh

Name of the Institution: PGIMER, Chandigarh

Name and address of the sponsoring (funding) agency: Not applicable

Documentation of the informed consent

I, … … … … … … … … …., have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in "…… "

1. I have read and understood this consent form and the information provided to me.
2. I have had my questions answered to my satisfaction.
3. I have had the consent document explained to me.
4. I have been explained about the nature of the study.
5. My rights and responsibilities have been explained to me by the investigator.
6. I have been advised about the risks associated with my participation in the study.
7. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in the hospital.

8. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to regulatory authorities, Government agencies, and ethics committee. I understand that they may inspect my original records.
9. My identity will be kept confidential if my data are publicly presented.
10. I have decided to participate in this research study. I am aware, that if I have any questions during this study, I should contact at one of the addresses listed above. By signing this consent from, I at test that the information given in this document.

Participant's Name: …….

For adult participant:

Name and signature / thumb impression of the participant:

(Name) (Signature) Date:

Time:

Name and signature of impartial witness (required for illiterate patients):

(Name) (Signature) Date:

Time:

Address and contact number of the impartial witness: …….

Name and signature of the Investigator or his representative obtaining consent:

(Name) (Signature) Date: Time: