Nursing Instructions for Study Medication
PERSuaDER Trial

PERSuaDER = PERi-operative **S**elective **D**econtamination of the **D**igestive tract to prevent severe infectious complications after **E**sophageal **R**esection

Rationale: esophagectomy is a highly complex surgical procedure that is associated with significant morbidity and mortality. Most postoperative complications are caused by infections (10-30%). It is believed that (micro-)aspiration of bacteria from the oropharyngeal and gastrointestinal tracts leads to pneumonia. Selective decontamination of the digestive tract (SDD) is a prophylactic antimicrobial strategy aimed at preventing postoperative infections, such as pneumonia. Pathogenic aerobic gram-negative rods and yeasts are reduced, while anaerobic, protective microbiota are preserved. SDD has been shown to reduce the risk of respiratory infections in an intensive care setting, but its effectiveness in esophageal surgery is still insufficiently proven.

Objective: Robust and prospective evaluation of SDD after esophagectomy as a protective strategy reducing postoperative pneumonia and other infectious complications, anastomotic leakage and mortality.

Study Design and Population: A randomized, controlled, open-label, multicenter trial involving 854 patients with primary resectable esophageal carcinoma ((y)cT1-4a N0-3 M0) scheduled for a transthoracic esophagectomy.

Primary Endpoint: The incidence of postoperative pneumonia within 30 days after surgery.

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Instructions for Administering SDD:

Dosage schedule:

Day -3 (at home)	Day -2 (at home)	Day -1 (at home)	Day of surgery	Day +1 (clinical)	Day +2 (clinical)	Day +3 (clinical)
4 times 08:00 AM 12:00 PM 18:00 PM 22:00 PM	4 times 08:00 AM 12:00 PM 18:00 PM 22:00 PM	4 times 08:00 AM 12:00 PM 18:00 PM 22:00 PM	1 dose in the morning **before surgery** 1 dose in the evening **after surgery**	4 times 08:00 AM 12:00 PM 18:00 PM 22:00 PM	4 times 08:00 AM 12:00 PM 18:00 PM 22:00 PM	4 times 08:00 AM 12:00 PM 18:00 PM 22:00 PM

Step-by-Step instructions:

Step 1: Clamp or close off the nasogastric tube.
Step 2: Shake both bottles well before use. **Do not mix them!**
Step 3: Open the brown bottle, containing the Fungizone solution.
Step 4: Attach the connector to the Fungizone bottle. **Do not use any other connectors!**
Step 5: Draw 5 mL of the Fungizone solution into the provided dosing syringe. The patient should take this orally, followed by 5 mL of the SDD suspension, which should also be taken orally.

General Information About Study Medication:

- The study medication consists of two boxes. Each box contains 1 bottle of amphotericin (brown) and 1 bottle of SDD suspension (transparent). First, use the bottles from one box before opening the second box.
- **Do not mix the amphotericin and SDD suspension bottles!** Administer them separately (it is acceptable to use the same syringe). As this is a drug study, we must comply with strict EU guidelines, which prohibit mixing these medications.
- **Clamp the nasogastric tube for 30 minutes** (if clinically justified, based on the nurse or doctor's clinical judgment).
- The patient must take the SDD **orally**, not via the nasogastric tube.
- Use the provided connector and syringe for administration. Keep the bottles, connector, and cap. The study team will collect the packaging on day 4 postoperatively. After the study period, we will weigh all the bottles to verify that the patients have taken the correct amount of SDD.
- If the patient is **intubated**, administer the SDD via the nasogastric tube (clamp for 30 minutes).
- **The patient must not use any "regular" SDD from the department, including SDD mouth paste.**
- If the patient accidentally did not receive the study medication, please contact the study team immediately (by phone or email, see below). It is better to skip a dose than to administer the wrong SDD, as this could compromise the integrity of the study.

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