UPDATE: FEEDS TRIAL

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UPCOMING RCT!

UCSF is participating in the FEEDS trial, a multicenter, parallel group, RCT. This trial aims to establish optimal preoperative fasting practice and prevent starvation in critically ill patients who receive tube feeding. Enrollment is expected to begin November 1st, 2025 & continue for about 2 years.

Hypothesis: In most mechanically ventilated patients, preoperative fasting is: 1) unnecessary due to presence of a secure airway and low incidence of aspiration, and 2) harmful due to exacerbation of pre-existing nutritional compromise.

Treatment arms: Study participants will be randomized 1:1 to one of the following pre-procedural interventions:

FASTING: stopping tube feeding for at least 8 hours prior to the scheduled procedure time

VERSUS

NON-FASTING: tube feeding will be continued until call for transfer to the procedure area

Primary Outcome: Days alive and free from mechanical ventilation on postoperative day 28.

Secondary Outcomes: recovery from critical illness, immediate perioperative safety, delivery of nutrition.

Inclusion criteria:

- Age >18
- Admission to ICU*
- Planned eligible procedure** with anesthesia care or nursing sedation
- Secure airway*** with no plans for its removal prior to procedure
- Current non-trophic (>10 mL/hr) tube feeding with no plans to discontinue prior to procedure for reasons other than preoperative fasting

*All ICU types eligible (cardiac, surgical, medical, neuro, mixed, etc.);
Eligible procedures defined below; * Secure airway is defined as cuffed endotracheal tube or cuffed tracheostomy tube.

Examples of eligible procedures:
Performed in operating room: repair of fractures, wound debridement, abdominal washout (without bowel resection or anastomosis), abdominal wall surgery, chest washout, vascular interventions (including endovascular)
Performed in procedural areas: placement of vascular catheters by interventional radiology, drainage of fluid collections, endovascular embolization or thrombectomy or thrombolysis, nephrostomy tube placement, cardiac catheterization, pulmonary angiography, imaging guided ablation of lesions, diagnostic imaging with anesthesia care or RN sedation
Performed at bedside: abdominal washouts, wound debridement, repairs of lacerations, drainage of abscess, bronchoscopies, transesophageal echocardiogram.

Exclusion criteria:

- Inability to obtain informed consent
- Inability to enroll and randomize >8 hours prior to planned procedure time
- Inability to deliver trial interventions
- Expected survival <48 hours
- Emergency procedures
- Burn patient
- GI tract procedure that requires fasting based on surgical indications
- Airway/Lung procedure that requires removal of ETT or tracheostomy tube
- Plan for prone or Trendelenburg positioning during most of procedure
- Major impairment of gastrointestinal motility or major structural disease of the gastrointestinal tract (e.g., gastroparesis, bowel obstruction, ileus, gastrointestinal bleeding)
- Plan for postoperative extubation in the procedure area
- Prisoner
- Pregnancy
- Refusal to enroll patient by treating physician
- ECMO at time of enrollment
- Chronic mechanical ventilation at pre-admission level of care

APP ROLE: APPs are asked to alert the study team if planning IR/bedside procedures for mechanically ventilated patients on tube feeds that may be eligible for this trial as these procedures can be hard to identify using APEX lists. Please feel free to reach out to Emily Brumsted, Genevieve Manahan, or Lee-Lynn Chen (voalte) if you think that there is a patient who may be eligible for enrollment.

Primary teams will be contacted prior to the patient or legally authorized representative being approached. The primary team attending physician and/or proceduralist will authorize the study team to consent the patient for enrollment.

A study coordinator or investigator will alert RNs to patients who have been randomized, and a nursing communication order will be placed to inform the RN if tube feeds should be held or continued prior to the procedure. Signs will also be placed on feeding tube pumps to instruct RNs on whether to continue tube feeds or hold for at least 8 hours prior to the procedure. If you have any questions, please feel free to reach out to study team members for more information via email. Looking forward to collaborating on this important trial.

Sincerely, Lee-lynn Chen MD, Genevieve Manahan MD. Emily Brumsted, MS, RD, CNSC