Study Title	**Timing of Gastrostoy in Acute Stroke (TOGAS)**
Funding I/C	PCORI, May 2026 submission
Study Description	To test whether a policy of early PEG tube placement (≤ 7 days post stroke onset) is non-inferior to the policy of deferred PEG tube placement (> 7 days post stroke onset) in stroke patients in whom PEG tube placement is anticipated. Demonstration of non-inferiority will allow broader incorporation of early PEG tube placement policy in stroke patients in the USA with subsequent reduction in length of hospitalization and improvement in patient centered outcomes. The project is consistent with PCORI's national priorities focused on comparative effectiveness of alternative treatment options in stroke patients with disability.
Study Design	Study Population and Research Setting(s): The trial will recruit stroke patients aged ≥18 years who, at third day of stroke onset, are likely to require PEG tube placement based on clinical stroke severity and lack of improvement in dysphagia on serial assessments at any of the participating 20 primary or comprehensive stroke centers to ensure broad representation of healthcare systems across the USA that manage ≥200 stroke patients a year, can perform PEG tube placement, and currently use a deferral period (of at least 7 days of stroke onset) prior to placement of PEG tube. These sites will be selected based on institutional support, clinician leader engagement, prior clinical trials experience, racial/ethnic and geographic diversity, and include those serving rural communities. Interventions/Comparators: Participating sites will maintain their existing policy of deferred PEG tube placement while in the control arm, and after crossover will adopt a policy of early PEG tube placement, defined as ≤ 7 days of stroke onset. The ≤7-day cutoff is supported by prior studies showing that the proportion of patients with dysphagia stabilizes by Day 3-7 post-stroke17 and that prognostic markers and swallowing evaluations at Day 3 predict prolonged dysphagia with >90% sensitivity and specificity. 4,18,19 Evidence from nine studies on PEG timing indicates that six demonstrated reductions in length and cost of hospitalization with PEG placement ≤ 7 days of admission/onset, whereas three studies of deferred placement (>7 days) found no such benefit. 20-28 Therefore, PEG tube placement ≤ 7 days of stroke onset represents the optimal time frame in which the need for long-term enteral feeding can be accurately determined, since swallowing prognosis is reliably established by this point. This window not only allows the procedure to be appropriately planned and safely performed, but also maximizes efficiency by reducing delays in nutrition, rehabilitation, and discharge planning, thereby improving patient outcomes while decreasing hospital length of stay and associated costs. Implementation of the early PEG tube placement policy will be evaluated using the Consolidated Framework for Implementation Research (CFIR) to identify barriers and facilitators influencing feasibility, acceptability, adoption, appropriateness, penetration, and sustainability using three monthly focus groups with investigators and local site personnel. Intervention delivery complexity-which affects planning, fidelity, and detection of outcome differences-will be systematically measured with the 6-item Intervention Delivery Complexity Tool, assessing both internal (e.g., workflow, training, intervention components) and external (e.g., health system variability, setting dependency, procedural steps) factors.29
IRB	Johns Hopkins University (sIRB)
Coordinating Center	Data Coordinating Center (DCC): Johns Hopkins University / BIOS Trial Innovation Center; Clinical Coordinating Center: University of Missouri
Study Length	5 years, 3 months for participants
Study Enrollment #	700
Eligibility Criteria	**Inclusion Criteria** Age ≥18 years Acute stroke (ischemic or hemorrhagic) By Day 3 post-stroke, expected to require PEG tube placement based on stroke severity and persistent dysphagia Informed consent obtained from patient or legally authorized representative **Exclusion Criteria** • Pre-existing PEG or gastrostomy tube • Contraindications to PEG placement (e.g., coagulopathy, abdominal pathology) • Participation in another interventional trial
Total # of Sites	20

Site Requirements	Study sites will need to have the following at their site to be considered: • Primary or comprehensive stroke center designation • Manage ≥200 stroke patients annually with capability to perform PEG tube placement • Currently use a deferred PEG placement policy (>7 days post-stroke onset)
Site Invesitgator Qualifications	Site Invesitigators should have the following: • Prior experience in clinical trials (preferred) • Institutional support and commitment to study participation
Key Timeline Dates:	The following dates are projections and subject to change: **Site Selection Decisions**: April 2027 (Subject to Change) **Site Selection Notifications:** August 2027 **Enrollment begins:** Q4 2027 (pending funding) **Last Patient/Last Visit:** Approximately 5 years after enrollment begins **Study Closure:** Approximately 6 months after last patient last visit