Essai Clinique

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Titre	PRO-ACTIVE: Comparing The Effectiveness of Prophylactic Swallow Intervention for Patients Receiving Radiotherapy for Head and Neck Cancer
Protocole ID	CTO1363
ClinicalTrials.gov ID	NCT03455608
Type(s) de cancer	ORL
Type étude	Support
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But étude	Dysphagia (difficulty swallowing) is a common and potentially life-threatening toxicity of radiotherapy (RT) for patients with head and neck cancer (HNC). HNC survivors have a 20-24 percent lifetime risk of pneumonia after RT, which is associated with a 42 percent excess risk of death in survivorship. Moreover, dysphagia predisposes individuals to malnutrition, and at least half of HNC patients require feeding tubes during RT. Patients are commonly referred for swallowing therapy with a speech pathologist. Some patients receive early intervention, before a swallowing problem begins—PRO-ACTIVE therapy. Other patients are monitored and prescribed dysphagia interventions only if and when a swallowing problem occurs—RE-ACTIVE therapy. Thus, REACTIVE therapy aims to reverse an already impaired swallowing ability, whereas PRO-ACTIVE therapy aims to prevent or reduce severity of dysphagia. These two broad categories of therapy represent the most common types of intervention offered to HNC patients across North America. Although there is single-institution evidence to support each practice, it is yet unknown which is most effective. To address this gap, the primary aim of this international, multi-site 3-arm pragmatic randomized clinical trial is to compare the effectiveness of PRO-ACTIVE (high and low intensity) versus RE-ACTIVE swallowing therapy among 952 patients with HNC planning to undergo RT, using duration of feeding tube dependence after RT as the primary outcome. Our secondary aim proposes to compare the relative benefit or harm of these swallowing interventions on secondary outcomes considered relevant to our stakeholder partners.
Critères d'éligibilité	• Adults ≥ 18 years of age diagnosed with head and neck malignancy • RT treatment planned for curative intent; and • Dispositioned to receive external beam radiotherapy dose ≥60 gray to bilateral fields at participating institution
Critères d'exclusion	• Distant metastasis at enrollment; or • Prior or planned total laryngectomy; or • Moderate/severe dysphagia at enrollment per baseline videofluoroscopy DIGEST grade ≥2 (as graded per central laboratory review)