Systemic Therapy of Open-label Prophylactic Pravastatin or Pentoxifylline/Tocopherol Prevention of Lymphedema Advancing to Eventual Fibrosis: an Interventional Registry-embedded Bayesian Randomized Trial for Radiation Sequelae (STOP4-LATE-FIBROSE)

NCT06494111

Status	RECRUITING
Phase	Phase 2
Sponsor	M.D. Anderson Cancer Center
Enrollment	295 participants

Key Eligibility Criteria

Inclusion (18)

- • Untreated T0-T4N0-3M0 oropharyngeal squamous carcinoma.
- Dispositioned to radiotherapy with prescribed dose to unilateral or bilateral neck(s).
- Creatinine clearance \>30mL/min
- Age e18 years. Because no dosing or adverse event data are currently available on the use of pentoxifylline/pravastatin in participants \<18 years of age, children are excluded from this study
- ECOG performance status d2 (Karnofsky e60%,)

... and 13 more (see full listing online)

Exclusion (10)

- Active liver disease (Child-Pugh class B-C), cirrhosis, nor active alcoholism.
- History of myopathy/rhabdomyolysis.
- History of acute myocardial infarction or severe coronary disease.
- Pregnant/post-menopausal, or male.
- History of diabetes mellitus.

... and 5 more (see full listing online)

Locations (1 total)

MD Anderson Cancer Center, Houston, Texas, United States