Study Title:
A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients with Head and Neck Cancer (1 credit)

ClinicalTrials.gov: Trial of Acupuncture for Radiation-Induced Xerostomia in Head and Neck Cancer (ACUPUNCTURE)

For Clinical Research Sites interested in participating in this study, please contact Robin Rosdhal by e-mail (rosdhal@wakehealth.edu) or by phone (336.713.6519).

PURPOSE:

- This study is being done to find out what effects, good and/or bad, acupuncture has on participants and their xerostomia caused by radiation therapy for the treatment of the cancer.

Study Type:

- Interventional

Study Design:

- *Allocation*: Randomized
- *Endpoint Classification*: Efficacy Study
- *Intervention Model*: Parallel Assignment
- *Masking*: Double Blind (Subject, Investigator, Outcomes Assessor)
- *Primary Purpose*: Treatment

Estimated Enrollment:	240
Study Start Date:	January 2016
Estimated Study Completion Date:	June 2018
Estimated Primary Completion Date:	December 2017 (Final data collection date for primary outcome measure)

Primary Outcome Measures:

- 9 Item Xerostomia Questionnaire:
  - Self-reported Xerostomia questionnaire completed prior to study randomization. Each item is scored on a scale of 0-10 with higher scores indicating greater dryness or discomfort due to dryness, yielding a total between 0 and 90.
  - *Time Frame*: Baseline
  - *Designated as safety issue*: No

Detailed Description:

Patients who have met all eligibility criteria will be randomized to standard oral hygiene, standard oral hygiene + true acupuncture twice weekly for 4 weeks, or standard oral hygiene + sham acupuncture twice weekly for 4 weeks by a form of adaptive randomization, called minimization, because simple randomization could result in covariate imbalances.

The acupuncture points will be at three sites on each ear (Shenmen, Point Zero, Salivary Gland 2-prime), a site on the chin (CV24), a site on each forearm (Lu7), a site on each hand (LI 1-prime), a site on each leg (K6), and one placebo needle at Gb32 for a total of 14 sites. All sites will be applied for 20 minutes. For body points, standardized techniques for location will be

utilized, which are based on anatomical landmarks as well as proportional measurements using the patient's own body. For example, finger breadth is based on each patient's middle finger, and the proportional unit of measure, the "cun," is defined as the distance between the two medial ends of the creases of the interphalangeal joints when the middle finger is flexed. Earpoint locations will mimic standard practice and be identified by the acupuncturists.

For more information, please follow the ClinicalTrials.gov link provided at the top of this page