Cancer Research Consortium of West Michigan
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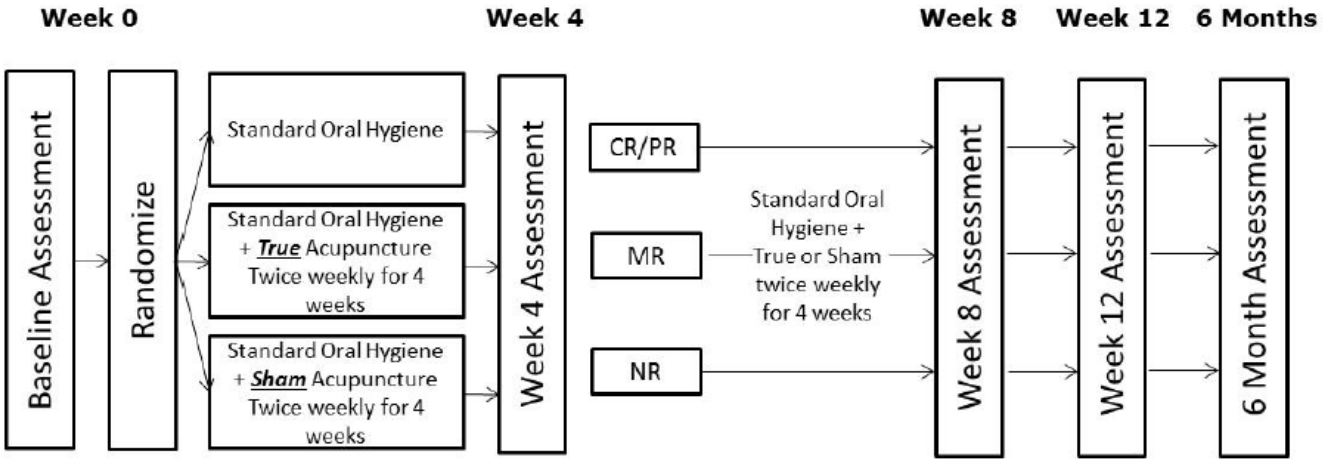
FAST FACTS

WF 97115: A Phase III Prospective Randomized Trial of Acupuncture for Treatment of Radiation-Induced Xerostomia in Patients with Head and Neck Cancer



INCLUSION CRITERIA

1. Must be at least 18 years of age and able to give informed consent.
2. Must be able to read, write and understand English.
3. Must have a diagnosis of head/neck cancer.
4. Must have received bilateral radiation therapy, and subsequently developed grade 2 or 3 xerostomia, according to modified RTOG scale:
   - Grade 0 – None
   - Grade 1 – Slight dryness of mouth (good response on stimulation and no significant dietary alterations necessary)
   - Grade 2 – Moderate dryness of mouth (poor response on stimulation and altered oral intake required such as frequent water, oral lubricants, or soft-moist foods)
   - Grade 3 – Complete dryness of mouth (no response on stimulation and difficult oral alimentation; IV fluids, pureed diet or tube feedings may be required)
   - Grade 4 – Fibrosis
5. Must have received external beam radiation at a mean dose of at least 24 Gy to one of the parotid glands. The other gland can receive less than 24 Gy.
6. Must have completed radiotherapy at least 12 months prior to entry.
7. Must have anatomically intact parotid and submandibular glands. A focused (head/neck) history and exam conducted by a physician or dentist within the past year is required.
8. Must be acupuncture naïve
9. Must have ECOG performance status of 0-2.

EXCLUSION CRITERIA

1. History of xerostomia, Sjogren's disease or other illness known to affect salivation prior to head/neck radiation.
2. Suspected or known closure of salivary gland ducts on either side.
3. Currently receiving or planning to use drugs, herbs, alternative medicines, or devices that could affect salivary production. Treatment known to affect salivation should be stopped at least 14 days prior to enrollment. Over the counter products used for salivary substitution are allowed, but will need to be discontinued for at least 24 hours prior to saliva and questionnaire data collection.
4. Have received any investigational new drug within the past 30 days or planning to receive such during the study period.
5. Active systemic infection or skin infection at or near the acupuncture sites.
6. Receiving chemotherapy during study period.

Baseline Assessments

After the patient has signed consent and all eligibility requirements are met, the patient will complete the following before being randomized to 1 of 3 study arms:

- Xerostomia Questionnaire (XQ), MD Anderson Symptom Inventory for Head and Neck Cancer (MDASI-HN) questionnaire, The Functional Assessment of Cancer Therapy (FACT-G), Acupuncture Expectancy Scale (AES), and Sialometry

Standard Oral Hygiene Arm:

Patients randomized to the Standard Oral Hygiene arm will receive standard care only. Patients will complete the following at each study visit as defined above:

- The Xerostomia Questionnaire (by phone if patient is unable to come to hospital for assessment)**,** MDASI-HN Questionnaire, FACT-G questionnaire**,** Sialometry**,** Toxicities**,** and Concomitant Medications

True Acupuncture and Sham Acupuncture Arms:

Patients randomized to the true acupuncture and sham acupuncture arms will receive standard care in regards to their xerostomia. In addition, patients will receive either true or sham acupuncture twice weekly for four weeks.

The following will be completed at each acupuncture visit:

Vital signs, Review of adverse events, Review of concomitant medications, Acupuncture treatment form

At the end of week 4 patients will complete:

The Xerostomia Questionnaire (by phone if patient is unable to come to hospital for assessment), MDASI-HN Questionnaire, FACT-G questionnaire, AES Questionnaire (week 4 only), Sialometry, Toxicities, Concomitant Medications, and Response Assessment

At 8 and 12 weeks and at 6 months after treatment, all acupuncture patients will complete the following:

The Xerostomia Questionnaire (by phone if patient is unable to come to hospital for assessment), MDASI-HN Questionnaire, FACT-G Questionnaire, Sialometry, Toxicities, Concomitant Medications