This study is currently recruiting participants. (see Contacts and Locations)

Verified April 2013 by John D. Archbold Memorial Hospital

Sponsor:
John D. Archbold Memorial Hospital

Information provided by (Responsible Party):
J. Steven Johnson, MD, John D. Archbold Memorial Hospital

ClinicalTrials.gov Identifier: NCT01824134

First received: April 1, 2013
Last updated: April 3, 2013
Last verified: April 2013

Aloe Vera on Irradiated Breast Tissue

Tracking Information

- **First Received Date** ICMJE: April 1, 2013
- **Last Updated Date** ICMJE: April 3, 2013
- **Start Date** ICMJE: October 2012
- **Estimated Primary Completion Date** ICMJE: October 2013 (final data collection date for primary outcome measure)

Current Primary Outcome Measures (submitted: April 3, 2013)
- **erythema** [Time Frame: one year] [Designated as safety issue: No]

Original Primary Outcome Measures
- Same as current

Change History
- Complete list of historical versions of study NCT01824134 on ClinicalTrials.gov Archive Site

Current Secondary Outcome Measures (submitted: April 3, 2013)
- **itching** [Time Frame: one year] [Designated as safety issue: No]

Original Secondary Outcome Measures
- Same as current

Current Other Outcome Measures ICMJE
- Not Provided

Original Other Outcome Measures ICMJE
- Not Provided

Descriptive Information

- **Brief Title** ICMJE: Aloe Vera on Irradiated Breast Tissue
A Phase III Double Blind Study on the Efficacy of Topical Aloe Vera Gel on Irradiated Breast Tissue

The investigators are testing two over the counter aloe vera gels on irradiated breast tissue.

Not Provided

Interventional

Phase 3

Allocation: Randomized
Intervention Model: Single Group Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Supportive Care

Irradiated Breast Tissue

- Other: Klean & Klear The Dandy Day Corp
- Other: The Skin Gel Herbal Answers, Inc

- Active Comparator: Klean & Klear aloe vera gel
  Intervention: Other: Klean & Klear The Dandy Day Corp
- Active Comparator: The Skin Gel aloe vera gel
  Intervention: Other: The Skin Gel Herbal Answers, Inc

Not Provided

* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.

Recruiting

50

October 2014

October 2013 (final data collection date for primary outcome measure)

Inclusion Criteria:
1. Women over 18 years of age who had undergone lumpectomy or partial mastectomy for breast cancer, and who then received postoperative radiation therapy using tangential fields, with or without a boost to the tumor bed. Chemotherapy as part of the treatment regimen was acceptable.
2. No major medical or psychiatric illness that might interfere with patient's completion of study requirements
3. Signed study-specific informed consent form prior to study entry

Exclusion Criteria:
1. Those requiring nodal radiation therapy were excluded.
2. Subjects who have a breast infection at the commencement of radiation treatment
3. Before randomization, subjects who have agreed to participate are asked if they are allergic to any topical preparation. Those allergic to aloe vera were ineligible.
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Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP