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Trial record **8 of 18** for: "aloe vera"

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# Aloe Vera on Irradiated Breast Tissue

**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
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

| Tracking Information | |
|---|---|
| First Received Date ICMJE | April 1, 2013 |
| Last Updated Date | April 3, 2013 |
| Start Date ICMJE | October 2012 |
| Estimated Primary Completion Date | October 2013 (final data collection date for primary outcome measure) |
| Current Primary Outcome Measures ICMJE (submitted: April 3, 2013) | erythema [ Time Frame: one year ] [ Designated as safety issue: No ]<br>since we are testing two over the counter products we wanted to wee if one tested better than the other |
| Original Primary Outcome Measures ICMJE | *Same as current* |
| Change History | Complete list of historical versions of study NCT01824134 on ClinicalTrials.gov Archive Site |
| Current Secondary Outcome Measures ICMJE (submitted: April 3, 2013) | itching [ Time Frame: one year ] [ Designated as safety issue: No ]<br>is there a difference in itching |
| Original Secondary Outcome Measures ICMJE | *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 |

| | |
|---|---|
| **Official Title** ICMJE | A Phase III Double Blind Study on the Efficacy of Topical **Aloe Vera** Gel on Irradiated Breast Tissue |
| **Brief Summary** | The investigators are testing two over the counter **aloe veras** on irradiated breast tissue. |
| **Detailed Description** | *Not Provided* |
| **Study Type** ICMJE | Interventional |
| **Study Phase** | Phase 3 |
| **Study Design** ICMJE | Allocation: Randomized<br>Intervention Model: Single Group Assignment<br>Masking: Double Blind (Subject, Investigator)<br>Primary Purpose: Supportive Care |
| **Condition** ICMJE | Irradiated Breast Tissue |
| **Intervention** ICMJE | • Other: Klean & Klear The Dandy Day Corp<br>• Other: The Skin Gel Herbal Answers, Inc |
| **Study Arm (s)** | • Active Comparator: Klean & Klear<br>**aloe vera** gel<br>Intervention: Other: Klean & Klear The Dandy Day Corp<br>• Active Comparator: The Skin Gel<br>**aloe vera** gel<br>Intervention: Other: The Skin Gel Herbal Answers, Inc |
| **Publications *** | *Not Provided* |

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

## Recruitment Information

| | |
|---|---|
| **Recruitment Status** ICMJE | Recruiting |
| **Estimated Enrollment** ICMJE | 50 |
| **Estimated Completion Date** | October 2014 |
| **Estimated Primary Completion Date** | October 2013 (final data collection date for primary outcome measure) |
| **Eligibility Criteria** ICMJE | Inclusion Criteria:<br>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.<br>2. No major medical or psychiatric illness that might interfere with patient's completion of study requirements<br>3. Signed study-specific informed consent form prior to study entry<br>Exclusion Criteria:<br>1. Those requiring nodal radiation therapy were excluded.<br>2. Subjects who have a breast infection at the commencement of radiation treatment<br>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. |

| | |
|---|---|
| **Gender** | Female |
| **Ages** | 18 Years and older |
| **Accepts Healthy Volunteers** | No |
| **Contacts** ICMJE | |
| **Location Countries** ICMJE | United States |

## Administrative Information

| | |
|---|---|
| **NCT Number** ICMJE | NCT01824134 |
| **Other Study ID Numbers** ICMJE | 12-09-008 |
| **Has Data Monitoring Committee** | No |
| **Responsible Party** | J. Steven Johnson, MD, John D. Archbold Memorial Hospital |
| **Study Sponsor** ICMJE | John D. Archbold Memorial Hospital |
| **Collaborators** ICMJE | *Not Provided* |
| **Investigators** ICMJE | *Not Provided* |
| **Information Provided By** | John D. Archbold Memorial Hospital |
| **Verification Date** | April 2013 |

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**