Limiting Chemotherapy Side Effects by Using Moxa

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators.
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ClinicalTrials.gov Identifier: NCT02781155

Recruitment Status : Unknown
Verified May 2016 by Beverley de Valois PhD LicAc FBAcC, East and North Hertfordshire NHS Trust.
Recruitment status was: Recruiting
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Sponsor:
East and North Hertfordshire NHS Trust

Collaborator:
British Acupuncture Council

Information provided by (Responsible Party):
Beverley de Valois PhD LicAc FBAcC, East and North Hertfordshire NHS Trust

Study Description

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Brief Summary:
This study investigates whether it is feasible to teach cancer patients undergoing chemotherapy to self-

administer daily moxibustion to reduce chemotherapy side effects. Moxibustion is a therapy used in traditional Chinese medicine that uses heat.

Condition or disease	Intervention/treatment	Phase
Breast Neoplasms Colorectal Neoplasms Genital Neoplasms, Female Toxicity Due to Chemotherapy	Other: Moxibustion	Phase 1 Phase 2

Detailed Description:

Chemotherapy drugs are used to treat cancer cells. However, they can also affect bone marrow and reduce the ability to make certain types of blood cells. Low white blood cell counts can leave patients vulnerable to infection. Low red blood cell counts can lead to anaemia and feelings of fatigue and weakness. Low platelet counts can lead to bruising and bleeding. Blood counts are therefore monitored. If they fall too low, the dose of chemotherapy may be reduced or the time between doses extended. This may affect survival as well as quality of life.

Research studies in China and the West suggest that moxibustion applied by a practitioner can improve blood counts and immunity, and reduce side effects of chemotherapy. Moxibustion (also called moxa) is a form of traditional Chinese medicine that uses heat to stimulate acupuncture points. This heat comes from a smouldering herb called mugwort, that is rolled into a cigar shape to gently warm the point. Many patients regard this as a pleasant, relaxing experience.

The researchers will teach patients to self-administer moxa to an acupuncture point just below the knee. This is a feasibility study to see if patients are willing and able to self-administer moxa daily throughout chemotherapy. Patients will keep a moxa diary to record their activity. The researchers will also use a questionnaire to assess whether patients see themselves as active managers of their health. This may help the researchers to screen suitable patients in future studies.

The researchers will also monitor blood counts, any delays or dose reductions to the chemotherapy, and any chemotherapy side effects. Participants will complete quality of life questionnaires at intervals during and after their chemotherapy.

If results are favourable, they will be used to design a randomised controlled trial comparing daily moxibustion with a "no treatment" control arm.

Study Design

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Study Type : Interventional (Clinical Trial)

Estimated Enrollment :	25 participants
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Supportive Care
Official Title:	Using Daily Self-administered Indirect Moxibustion to Zusanli St-36 to Reduce Chemotherapy Induced Pancytopenia: a Feasibility Study
Study Start Date :	February 2016
Estimated Primary Completion Date :	January 2017
Estimated Study Completion Date :	September 2017

Resource links provided by the National Library of Medicine

Genetics Home Reference related topics: Breast cancer

Genetic and Rare Diseases Information Center resources: Granulocytopenia

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Self administration of moxibustion Participants will be taught to self administer moxibustion to the acupuncture point Zusanli St-36, and apply it daily throughout their chemotherapy treatments	Other: Moxibustion Participants are taught to self administer moxibustion to acupuncture point Zusanli St-36 daily throughout the course of their chemotherapy Other Name: Moxa

Outcome Measures

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Primary Outcome Measures :

1. Adherence to moxa regimen assessed by Daily Moxa Diary [Time Frame: 21 days after last chemotherapy cycle]

   The primary aim of this study is to assess the feasibility of teaching cancer patients undergoing chemotherapy in the National Health Service (NHS) to self-administer daily indirect moxibustion to St 36 Zusanli, according to a protocol that begins ideally 7 to 10 days prior to the first chemotherapy cycle and continues until 21 days after the final chemotherapy cycle. Participants will complete a Daily Moxa Diary to record their adherence to the daily protocol. They will be asked also to log any days they miss, and give reasons why.

Secondary Outcome Measures :

1. Blood counts, specifically white blood cells, neutrophils, haemoglobin, and platelets [Time Frame: Throughout chemotherapy, on 1st day of each cycle, according to chemotherapy schedule. This is usually fortnightly for colorectal (Days 1, 15, 19, 43, 57, 71, 85, 99) and 3-weekly for breast and gynaecologic cancers (Days 1, 22, 43, 64, 85, 106)]

   Blood counts will be collected from the participants' medical notes to monitor incidents of neutropenia, anaemia, or thrombocytopenia.

2. Variation to planned chemotherapy schedule [Time Frame: Throughout chemotherapy, on 1st day of each cycle, according to chemotherapy schedule. This is usually fortnightly for colorectal (Days 1, 15, 19, 43, 57, 71, 85, 99) and 3-weekly for breast and gynaecologic cancers (Days 1, 22, 43, 64, 85, 106)]

   Any delays in chemotherapy schedule and the reasons why will be collected from the participants' medical records

3. Chemotherapy related toxicities [Time Frame: Throughout chemotherapy, on 1st day of each cycle, according to chemotherapy schedule. This is usually fortnightly for colorectal (Days 1, 15, 19, 43, 57, 71, 85, 99) and 3-weekly for breast and gynaecologic cancers (Days 1, 22, 43, 64, 85, 106)]

   Data will be collected from the participants' medical records, specifically the Common Terminology Criteria for Adverse Events (CTCAE), which is the standard form used in the Chemotherapy Suite to record information about any toxicities experienced by the patient resulting from chemotherapy (such as fatigue, vomiting, etc)

4. Health related quality of life (HRQOL) [Time Frame: At Baseline, cycles 2, 3, and 6 (or final

cycle), and one month after final cycle: typically Days 15, 29, 71, 127 for colorectal; Days 22, 43, 106, 134 for breast and gynaecological cancers]

The study will seek to identify changes in quality of life, to help with hypothesis generation for future studies. Validated questionnaires from the Functional Assessment for Cancer Therapy (FACT) will be used, including:

FACT-G: a 27 item compilation of general questions covering physical, social/family, emotional and functional wellbeing; FACT-N: a 19-item neutropenia subscale designed to capture symptoms and impact on HRQOL related to neutropenia; FACT-An - a 20-item questionnaire assessing fatigue and anaemia-related concerns in people with cancer.

5. Patient self-management [Time Frame: At Baseline, cycle 3, and one month after final cycle: typically Days 29 and 127 for colorectal; Days 43 and 134 for breast and gynaecological cancers]

   Patients with a high level of activation are likely to engage in positive health behaviours and participate in managing their health conditions more effectively. The Patient Activation Measure (PAM) will be used to explore whether it is possible to identify patients who will be most likely to follow a daily healthcare regimen.

6. Safety assessed by all incidents including allergies, burns, and other accidents [Time Frame: Through study completion, spanning 16 to 28 weeks depending on chemotherapy regimen]

   The safety of moxibustion is under-reported in the literature. The researchers will monitor and record all incidents affecting safety, including allergies, burns, and other accidents

7. Incidents of additional interventions administered as prophylaxis or therapy to maintain or improve blood counts [Time Frame: Through study completion, spanning 16 to 28 weeks depending on chemotherapy regimen]

   The researchers will record whether participants are taking or having therapies that affect blood cell counts, such as steroids, iron supplements and other dietary supplements as prophylaxis, or blood and platelet transfusions to improve low blood counts.

Eligibility Criteria Go to

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years to 75 Years (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- with breast, gynaecologic, or colorectal cancer who are prescribed radical or adjuvant chemotherapy in the early disease setting, or first or second line chemotherapy is in the metastatic setting
- about to commence a course of chemotherapy for which granulocyte-colony stimulating factor (G-CSF) is not routinely indicated
- with a life expectancy of more than six months
- with blood cell counts within the normal range
- with calculated creatinine levels of ≥ 50ml/min
- English speaking
- able to understand instructions for self-administration of moxibustion and carry out the procedure
- able to give informed consent

Exclusion Criteria:

- having a haematological cancer diagnosis
- prescribed a chemotherapy regimen for which G-CSF is indicated
- having third or fourth line chemotherapy
- having metastatic bone cancer
- who have concomitant severe medical problems preventing participation
- with cognitive impairment that would impact participant's ability to safely administer self-

moxibustion

- having renal dysfunction
- with lymphedema in the lower body.

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02781155***

Contacts

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Locations

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British Acupuncture Council

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More Information

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Plan to Share IPD: No

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Health related quality of life
Moxibustion
Cancer
Chemotherapy
Neutropenia
Anaemia
Thrombocytopenia
Self management
Wellbeing

Additional relevant MeSH terms:

Neoplasms
Breast Neoplasms
Colorectal Neoplasms
Genital Neoplasms, Female
Neoplasms by Site
Breast Diseases
Skin Diseases
Intestinal Neoplasms
Gastrointestinal Neoplasms
Digestive System Neoplasms
Digestive System Diseases
Gastrointestinal Diseases
Colonic Diseases
Intestinal Diseases
Rectal Diseases
Urogenital Neoplasms