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The effectiveness and cost effectiveness of acupressure for the control and management of chemotherapy-related acute and delayed nausea

Submission date
21/04/2008

Recruitment status
No longer recruiting

Registration date
03/06/2008

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-acupressure-to-help-relieve-sickness-from-chemotherapy

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 07/31/02

Study information

Scientific Title
The effectiveness and cost effectiveness of acupressure for the control and management of chemotherapy-related acute and delayed nausea

Acronym
ANCHoR

Study objectives
Primary objective:
1. To assess the clinical effectiveness of self-acupressure using wristbands in addition to standard care in the management of chemotherapy-induced (acute and delayed) nausea compared to patients receiving standard care with sham acupressure wristbands and standard care alone.

Secondary objectives:
2. To assess the cost effectiveness and extent of use of usual care in patients using acupressure wristbands in addition to standard care for the management of chemotherapy-induced nausea compared to patients receiving standard care with sham acupressure wristbands and standard care alone.
3. To assess the level of quality of life in patients using acupressure wristbands in addition to standard care in the management of chemotherapy-induced nausea and vomiting compared to patients receiving standard care with sham acupressure wristbands and standard care alone.
4. To assess the clinical effectiveness of self-acupressure using wristbands in addition to standard care in the management of chemotherapy-induced (acute and delayed) vomiting compared to patients receiving standard care with sham acupressure wristbands and standard care alone.
5. To ascertain for which emetogenic level of chemotherapy regimens (i.e. high, moderate or low emetogenic chemotherapy) self-acupressure using wristbands in addition to standard care is more or less effective in terms of nausea compared to patients receiving standard care with sham acupressure wristbands and standard care alone.
6. To ascertain whether any improvement in chemotherapy-induced nausea and vomiting from using acupressure wristbands is different in males and females.
7. To ascertain whether there is an age effect from the use of acupressure wristbands in relation to chemotherapy-induced nausea and vomiting.

Protocol in: http://www.hta.ac.uk/protocols/200700310002.pdf

Please note that as of 24/02/09 the acronym of this trial was amended; the initial acronym at the time of registration was: CART.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved by Nottingham 1 Multicentre Research Ethics Committee

Study design
Multicentre, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chemotherapy-related acute and delayed nausea

Interventions
This trial is testing the effect of acupressure wristbands using two acupressure groups and a standard care group (three-arm trial). In the first acupressure group, in addition to standard antiemetics, patients will be provided with a pair of SeaBand™ wristbands (Sea-Band Ltd, UK). These bands are elastic wristbands with a 1 cm protruding round plastic button (stud). These are available in two sizes, a standard one and a larger one. Patients wear the wristband with the stud pressing the P6 acu-point, which is located on the anterior surface of the forearm, approximately three-finger width up from the crease of the wrist between the tendons of the palmaris longus and flexor carpi radialis. Patients will be provided with a pair of acupressure wristbands and they will be instructed to wear them on both arms and take them off only when showering/bathing. An instruction sheet with a picture of point P6 and how to locate the point will also be provided to patients. Patients will be instructed to wear the wristbands from the morning before chemotherapy administration and for the subsequent 6 days (total 7 days).

In the second acupressure group, in addition to standard antiemetics, patients will be provided with a pair of the identical appearing wristbands, with the only difference being that the sham wristband will have a flat button in place of the protruding stud, thus exerting no pressure on the P6 point.

The standard care group will receive standard antiemetics alone. Standard antiemetics for all three groups will be based on the ASCO and MASCC international antiemetic guidelines with the exception of NK1 receptor antagonists (i.e. aprepitant) recommended in highly emetic chemotherapy, which is not available currently in the NHS. Hence, for highly emetic chemotherapy, patients should receive a 5-HT3 receptor antagonist (i.e. Zofran® 8 mg) and dexamethasone 8 mg intravenously before chemotherapy and the same orally for 3 days post chemotherapy; for moderately emetogenic chemotherapy a 5-HT3 receptor antagonist (Zofran® 8 mg) and dexamethasone 8 mg intravenously before chemotherapy and a 5-HT3 receptor

antagonist or dexamethasone (preferred) for 2 days post-chemotherapy; and for low emetogenic chemotherapy dexamethasone 8 mg before chemotherapy and no other treatment post-chemotherapy (Kris et al, 2006; Roila et al, 2006). All patients will receive rescue antiemetics if nausea and/or vomiting is persistent and fail to respond to the antiemetic treatment (i.e. severe nausea or greater than 5 vomiting episodes), based on the experience of each clinician (as agreed guidelines for rescue antiemetics have not been developed to date).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Nausea experience, assessed by the Rhodes Index of Nausea and Vomiting on following days of chemotherapy: -1, 0, 1, 2, 3, 4, 5, 6 (4 cycles)

Secondary outcome measures
1. Vomiting experience, assessed by the Multinational Association of Supportive Care in Cancer (MASCC) Antiemesis Tool (MAT) on Day 10 of chemotherapy cycle (4 cycles)
2. Nausea and vomiting occurrence, assessed by the Multinational Association of Supportive Care in Cancer (MASCC) Antiemesis Tool (MAT) on Day 10 of chemotherapy cycle (4 cycles)
3. Quality of Life, assessed by the Functional Assessment of Cancer Therapy (FACT-G) at baseline and on Day 10 of chemotherapy cycle (4 cycles)
4. Costs

Overall study start date
01/11/2008

Completion date
31/10/2010

Eligibility

Key inclusion criteria
1. Patients of either gender and older than 16 years old
2. Patients scheduled to receive their first chemotherapy cycle
3. Patients scheduled to receive highly, moderately and low emetogenic chemotherapy (as per American Society of Clinical Oncology [ASCO] and Multinational Association of Supportive Care in Cancer [MASCC] classifications)
4. Patients scheduled to receive a chemotherapy regime given as a single administration at the beginning of the cycle repeated in 3-week cycles
5. Patients who are acupressure wristband-naïve (in terms of never having tried for themselves such a wristband, although they may have seen or heard about such wristbands)
6. Patients with any cancer diagnosis receiving adjuvant chemotherapy
7. Patients receiving chemotherapy as outpatients
8. Patients willing to participate in the study and be randomised into one of the three study groups

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
699

Total final enrolment
500

Key exclusion criteria
1. Patients scheduled to receive radiotherapy concurrently with chemotherapy and during the assessment period of four cycles for each patient
2. Patients unable to self care (i.e. unable to use wristbands appropriately; mental incapacity preventing continuous and optimal use of wristbands) as judged by the investigators
3. Patients with liver disease (as nausea is common presenting symptom)
4. Patients with metabolic risk factors for nausea (i.e. electrolyte imbalances causing nausea /vomiting)
5. Patients with mechanical risk factors for nausea (i.e. intestinal obstruction)
6. Patients receiving chemotherapy regimens as inpatients
7. Patients experiencing nausea and/or vomiting due to use of opioids
8. Patients with lymphoedematous arms
9. Patients with chronic alcohol use (as it is associated with minimal levels of nausea and/or vomiting)

Date of first enrolment
01/11/2008

Date of final enrolment
31/10/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Nursing
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2013		Yes	No
Results article	results	01/01/2014		Yes	No
Plain English results			26/10/2022	No	Yes