Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Neiguan Point (p6) Acupressure with Wristband on Postoperative Nausea, Vomiting, and Comfort Level: A Randomized Controlled Study

Protocol summary

Summary
Aim: To determine how wrist pericardium 6-point (P6) Neiguan acupressure application with wristband affects nausea, vomiting, and comfort level at postoperative period. Background: Nurses have a responsibility to seek solutions in order to prevent nausea and raise patient's comfort at the postoperative period, and to test the practicality of these solutions. Design: A randomized, controlled experimental study Methods: The study was implemented at an obstetrics hospital. Data were collected in 2013, between February 1st and July 28th. The study was conducted on 97 patients (47 experimental and 50 controls) who underwent gynecological surgery other than Caesarian section. In the experimental group, acupressure with wristband was applied during the first 12 hours following operation. The control group received anti-emetics during and after operation.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2016081229311N1**
Registration date: **2016-08-24, 1395/06/03**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2016-08-24, 1395/06/03

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Recruitment status
Recruitment complete
Funding source
Investigator

Expected recruitment start date
2013-02-02, 1391/11/14
Expected recruitment end date
2013-07-01, 1392/04/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Neiguan Point (p6) Acupressure with Wristband on Postoperative Nausea, Vomiting, and Comfort Level: A Randomized Controlled Study

Public title
The Effect of Neiguan Point (p6) Acupressure with Wristband on Postoperative Nausea, Vomiting, and Comfort Level: A Randomized Controlled Study
Purpose
Prevention
Inclusion/Exclusion criteria
Age between 18-65 years, Patient underwent gynecological operation; Operation was performed under general anesthesia; The patient had no cognitive; sensory or verbal communication issues; Patient volunteered to participate in the study.

Age
From **18 years** old to **64 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **97**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Objective and design of the study The study was designed as a randomized-controlled experimental study to determine the effect of wrist P6 acupuncture point acupressure application with wristband on nausea, vomiting, and comfort level at the postoperative period. The following hypotheses were tested: H1A: Wrist P6 (Neiguan) acupuncture point acupressure application with wristband is effective as pharmacological methods in prevention of postoperative nausea. H1B: Wrist P6 acupuncture point acupressure application with wristband is effective as pharmacological methods in prevention of postoperative vomiting. H1C: Wrist P6 acupuncture point acupressure application with wristband enhances patient comfort. Study variables: Wrist P6 acupuncture point acupressure application with wristband is the independent variable of the study. Dependent variables are nausea, vomiting, and comfort level. Study population and sampling method The study population consists of patients who underwent a gynecological surgery other than Caesarian section (A, B, and C group operations) in an obstetrics hospital within the province of Bursa in Turkey. The population size was determined by reviewing the year 2011’s data, which showed that a total of 4,946 operations (A, B and C group) had been performed in the hospital that the study was conducted. A review of the literature showed that the incidence of nausea following gynecological operations varied between 58-77% (Kaya et al., 2010). When the population size was 4,946 and incidence of nausea was as 58%, the study sample size was calculated to be 92, which was within 5% significance level and 10% error margin. Accounting for possible issues that may occur during data collection period, an additional 8 patients were added to the sample size; thus, the final sample size was determined as 100. However, in the experimental group, 2 patients received anti-emetics, and one patient was discharged earlier than planned. Therefore, 3 patients from the experimental group were excluded from the study. In the end, there were 47 patients in experimental group and 50 patients in control group. Data collection tools Patient Information Form: This form contains personal information such as age, height, weight, health insurance, use of antiemetic drug during the last 24 hours, presence of any disease, or complaints, and also type and duration of anesthesia. State - Trait Anxiety Inventory (STAI): It was developed by Spielberger et al. (1970) for assessment of state and trait anxiety levels. Öner and Le Compte (1985) performed reliability and validity studies of this scale in Turkish population. The scale comprises two separate sections made of a total of 40 items, and was designed based on two factor anxiety concept. The first 20 items were used to assess state anxiety level, whereas the latter 20 items were for assessment of trait anxiety levels. Possible scores from both subscales range from 20 to 80 (Alacacıoğlu et al., 2007). Higher scores suggest a greater level of anxiety. Data for STAI was obtained from the experimental and control groups at the hospital admission. Nausea and Vomiting Follow-up Form: It was used to document intensity of nausea (0-10 point visual analog scale) and presence of vomiting (1: present, 2: absent) at the following intervals postoperatively: 0-2, 2-6, 6-12, 12-24 and 24-48 hours. Thus, the group that used wristband (experimental group) and the group that received anti-emetics according to the institution's protocol/physician order (control group) were compared in terms of intensity of nausea and presence of vomiting. Perianesthesia Comfort Questionnaire (PCQ): It was developed by Kolcaba and Wilson (2002), and validity and reliability study for Turkish version was conducted by Üstündağ and Eti Aslan (2010). The questionnaire was comprised of 24 items questioning self-comprehension and feelings that reflected general thought process before and after the surgical intervention. The total score was divided by the number of items to determine the mean value, and the result was expressed in a 6-point Likert scale. Lower scores indicated bad comfort, while higher scores indicated good comfort. Data for PCQ was obtained from both the experimental and control groups at the 12-hours post-operation. General Comfort Questionnaire (GCQ): It was developed by Kolcaba (1992), and validity and reliability study for Turkish version was conducted by Kuğuoğlu and Karabacak (2004). GCQ was designed based on the taxonomic concept, which included three types of comfort and four contexts that constitute the theoretical components of comfort. It was used to determine patient demands, and to assess achievement of desired comfort level that was expected after nursing interventions aimed at providing comfort. Maximum achievable score was 192, and minimum score was 48. Lower scores indicate lack of comfort, and higher scores indicate high comfort (Kuğuoğlu ve Karabacak 2008). Data for GCQ was obtained from both experimental and control group patients at the time of their discharge from hospital.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Uludağ University Faculty of Medicine Clinical Research Ethics Committee

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Uludag University Medical Faculty Deanery, 16059, Nilüfer/BURSA

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Postal code
16059

Approval date
2013-02-01, 1391/11/13

Ethics committee reference number
B.30.2.ULU.0.20.70.02-050.99/2

Health conditions studied

1

Description of health condition studied
Postoperative nausea and vomiting

ICD-10 code
Z48.9

ICD-10 code description
Surgical follow-up care, unspecified

Primary outcomes

1

Description
Nausea, vomiting, and comfort level at the postoperative period

Timepoint
Postoperative period

Method of measurement
This was a single-center, randomized-controlled experimental study conducted in the Turkey.

Secondary outcomes

1

Description
Nausea, vomiting, and comfort level at the postoperative period

Timepoint
Postoperative period

Method of measurement
This was a single-center, randomized-controlled experimental study conducted in the Turkey.

Intervention groups

1

Description
By screening the list of patients to be operated, those patients who met study inclusion criteria were determined. Those who were selected for enrollment in the study were informed about nausea occurring at the postoperative period, and about acupressure or antiemetic application that were used to prevent it. They were given written and verbal information about the study procedure. Individuals volunteering to participate in the study signed the Informed Voluntary Consent Form. Enrolled patients were randomly divided into patient and control groups by drawing lots. Consequently, the Patient Information Form and State-Trait Anxiety Inventory were filled; and groups were evaluated for presence of any difference. At postoperative period; Experimental Group: Within the first 12 hours after the operation, acupressure with wristband was applied to patient group. Anesthesiologists were informed of these patients group to make sure that they were not administered anti emetics intra-operatively. Intensity of nausea and presence of vomiting at the postoperative period were documented on the Nausea and Vomiting Follow-up Form. In case intensity of nausea did not decrease or vomiting persisted, then patient's physician was informed, and anti-emetics ordered by the physician were administered to the patient. In such a case, the patient was excluded from the experimental group. Two patients were excluded from the experimental group due to these reasons. Thus, any harm to the patient was prevented, and all arrangements required for patients to have optimum benefit from care-treatment interventions were provided. Control Group: The protocol in the hospital where the study was conducted is that all patients undergoing surgery (including A, B, and C group) are administered anti-emetics intraoperatively. Therefore, all patients in the control group received intra-operative anti-emetics. Additionally, patients in the control group received anti-emetics within the first 12 hours after operation, as appropriate to the clinical routine (ordered by the physician). Intensity of nausea and presence of vomiting were documented on the Nausea and Vomiting Follow-up Form. After 12 hours from the operation, PCQ was applied to both the experimental and control groups, in order to determine comfort levels before and after operation. Additionally, the comfort level for each person at the time of discharge was assessed with GCQ in both groups.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tek Grup
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty