

Title: Evaluation of the effect of acupuncture combined with antiemetics in the prophylaxis of chemotherapy-induced nausea and vomiting in breast cancer.

This is a study protocol that aims to evaluate the effect of acupuncture combined with antiemetics in the prevention of nausea and vomiting induced by chemotherapy in breast cancer patients. Breast cancer is a prevalent disease in Brazil, with over 66,000 cases diagnosed per year. Chemotherapy can significantly reduce the recurrence and mortality of breast cancer, but its side effects, particularly chemotherapy-induced nausea and vomiting (CINV), are still a challenge for patients and healthcare professionals. CINV can affect up to 80% of patients who do not receive antiemetic prophylaxis and compromise the continuity and effectiveness of the treatment.

The proposed study is a pilot project that will compare the response of standard prophylaxis with the same treatment plus acupuncture in CINV. It will be a unicentric, prospective, randomized study with cross-over of case/control groups. Thirty breast cancer patients receiving adjuvant/neoadjuvant chemotherapy with high emetogenic potential (doxorubicin) will be divided into two groups: control group (medication prophylaxis only) and intervention group (medication prophylaxis + acupuncture).

Metodology

The study will be conducted at the Hospital de Base in São José do Rio Preto, São Paulo, Brazil, and recruitment of patients will start in February 1st 2023. The chemotherapy regimen consists of four sessions with a 14- to 21-day interval between each, and antiemetic medication will be administered 15 to 30 minutes before chemotherapy (intravenous dexamethasone 16 mg and ondansetron 20 mg in 100 ml of saline solution). The control group will receive only medication prophylaxis during the first two sessions, while the intervention group will receive medication prophylaxis plus acupuncture.

The study will be a randomized controlled trial, and the primary endpoint will be the difference in response to the antiemetic prophylaxis between the two groups, evaluated by the frequency and intensity of CINV measured by FLIE (Functional Living Index-Emesis). The study aims to evaluate the effectiveness and safety of acupuncture as an adjuvant therapy in breast cancer patients receiving chemotherapy.

The proposed study involves comparing the effectiveness of standard prophylactic medication in combination with acupuncture versus the use of medication alone in the treatment of chemotherapy-induced nausea and vomiting. The control group will receive only medication in the first two chemotherapy sessions, while the intervention group will receive medication and acupuncture in the first two sessions. After the second session, the groups will be crossed, with the control group receiving acupuncture and medication in the last two sessions and the intervention group receiving only prophylactic medication in the last two sessions.

The acupuncture protocol involves the use of 9 systemic acupuncture points and 7 auriculotherapy points. The points are: PC6 (Pericardium 6), ST36 (Stomach 36), LR3 (Liver 3), LI4 (Large Intestine 4) bilaterally, and CV12 (Conception Vessel 12), and will be applied 30 minutes before starting chemotherapy. The participant will receive a crisis diary to record the frequency and intensity of nausea and vomiting for 2 days (1st and 5th days after chemotherapy) for evaluation of acute and delayed response. The FLIE questionnaire will be used to measure the CINV status, evaluating the effects of nausea and vomiting and their potential to affect the patient's daily activities.

INCLUSION CRITERIA:

- Female gender

- Age > 18 years

- Diagnosis of primary breast cancer
- Undergoing AC chemotherapy protocol (doxorubicin + cyclophosphamide)

EXCLUSION CRITERIA:

- Age < 18 years
- Illiteracy
- Presence of another primary cancer
- Presence of metastasis
- Presence of skin lesions/inflammations at the needling site
- Patient refusal

Expected primary outcome:

- Evaluation of the effectiveness of acupuncture in combination with antiemetics in preventing chemotherapy-induced nausea and vomiting in breast cancer using the FLIE questionnaire.

Expected secondary outcomes:

- Assessment of the frequency and severity of nausea and vomiting in both groups;
- Appraisal of the safety and tolerability of acupuncture in combination with antiemetics.