Topical Capsaicin Cream for Treatment of Suspected Cyclical Vomiting Syndromes

NCT03223350

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Study Design and Setting

This randomized, double-blind, placebo-controlled pilot trial was performed at an urban academic trauma center hospital with 100,000 annual ED visits. The study was approved by the institutional review board and registered with the National Library of Medicine (NCT03223350). Research team members screened patients using the electronic medical record system. We obtained written informed consent from all participants. Patients were enrolled between December 2017 and July 2019.

All adult patients (age ≥ 18 years) presenting with a suspected exacerbation of CHS and had active vomiting or nausea in the ED were eligible. Exclusion criteria were: minors (< 18 years old), pregnancy, known allergy to capsaicin or hot peppers, those with resolution of nausea prior to randomization, outpatient use of prescription antiemetics within the past 24- hours, acute infectious or surgical abdominal conditions, and inability to provide informed consent. The original protocol excluded patients that received any antiemetic medication in the ED prior to enrollment. Half-way through the trial, we made a protocol change that removed this exclusion criteria and allowed enrollment of patients that received an antiemetic medication in the ED prior to randomization as long as nausea was still present. We made this protocol change due to the difficulty obtaining consent and enrolling symptomatic patients prior to receiving standard antiemetic therapy.

Interventions, Randomization, and Blinding

Research team members assessed eligibility among all patients who presented with suspected CHS. Any potentially eligible female patients of childbearing age had to have a pregnancy test performed prior to enrollment. We randomized patients that provided informed consent to the experimental or control group using REDCap database (Research Electronic Data Capture, Vanderbilt University). Randomization used 1:1 allocation and stratified by gender. The treatment consisted of five grams of topical 0.1% capsaicin cream, and the placebo consisted of a moisturizing cream. The study team pre-packaged the capsaicin and placebo creams in identical single-dispensing tubes and coded each with a study identification number. The capsaicin cream and the placebo were identical in appearance and had no scent. An ED nurse applied study medication cream once to the abdomen in a uniform manner. The treating physicians, research team members, and patients were blinded to study drug allocation. In addition to study medication, patients received conventional therapy, which was determined by the treating physician independent of study enrollment.

Methods and Measurements

Research team members collected relevant patient demographic, clinical, and treatment data and entered data into a secure REDCap. We measured the intensity of the patient's nausea upon randomization and at 30- and 60-minutes following application of study medication. For nausea assessment, we used a previously validated visual analog scale (VAS) that ranged from 0 to 10 cm (10 being most severe).18,19 A research team member remained at the patient's bedside for the first 60 minutes to assess for any immediate adverse events. Additionally, the patient was assessed for any adverse events over the entire course of the patient's ED stay and, later, through a phone call at 30 days.

Outcomes

The primary outcome was the patient's reported nausea on the VAS at 30 minutes following study medication application. Secondary outcomes were the patient's reported nausea and percent change from baseline at 60 minutes, disposition status (hospital admission or discharge), and the need for rescue anti-emetic medication. The 30- and 60-minutes outcome assessment times were based on clinical experience that capsaicin has a rapid effect (<30 minutes) but may have a delayed maximum effect. Hospital admission included placement on observation or inpatient units.