



Cannabinoids for Pain Control During Medical Abortion

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. **▲** [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier:

NCT03604341

[Recruitment Status](#) ⓘ: Not yet recruiting

[First Posted](#) ⓘ: July 27, 2018

[Last Update Posted](#) ⓘ: July 30, 2018

See [Contacts and Locations](#)

Sponsor:

Oregon Health and Science University

Collaborator:

Society of Family Planning

Information provided by (Responsible Party):

Katie Alton, MD, Oregon Health and Science University

[Study Details](#)[Tabular View](#)[No Results Posted](#)[Disclaimer](#)[How to Read a Study Record](#)

Study Description

Go to **Brief Summary:**

The objective of this study is to determine if a synthetic cannabis derivative, dronabinol, in addition to ibuprofen, decreases maximum pain scores compared to ibuprofen and placebo in women undergoing medical abortion. Results of this study will help providers counsel patients regarding cannabis use during medical abortion.

Condition or disease ⓘ	Intervention/treatment ⓘ	Phase ⓘ
Medical Abortion Pain	Drug: Dronabinol 5mg Cap Other: Placebo	Phase 4

Detailed Description:

This is a randomized, double-blind, placebo-controlled trial comparing pain levels in women undergoing medical abortion with one of two regimens: ibuprofen 800mg and a 5mg oral dronabinol versus ibuprofen 800mg and placebo given at the time of misoprostol administration. This study will include 62 women undergoing medical abortion. Women will be randomized to dronabinol 5mg oral versus placebo. The primary outcome will be maximum reported pain score within 24 hours of misoprostol administration.

Study Design

Go to [Study Type](#) ⓘ: Interventional (Clinical Trial)Estimated [Enrollment](#) ⓘ: 62 participants

Allocation: Randomized

Intervention Model: Single Group Assignment

Masking: Double (Participant, Investigator)

Primary Purpose: Treatment

Official Title: Cannabinoid Analgesia for Medical Abortion: A Randomized Controlled Trial

Estimated [Study Start Date](#) ⓘ: August 2018Estimated [Primary Completion Date](#) ⓘ: March 2019Estimated [Study Completion Date](#) ⓘ: June 2019

Resource links provided by the National Library of
Medicine



[Drug Information](#) available for: [Dronabinol](#)

[U.S. FDA Resources](#)

Arms and Interventions

Go to

Arm ⓘ	Intervention/treatment ⓘ
Experimental: Gestational age up to 10w0d - Dronabinol Women with gestational age up to 10 weeks 0 days will be randomized to Dronabinol 5mg Cap or placebo	Drug: Dronabinol 5mg Cap Subjects randomized to Dronabinol 5mg Cap and ibuprofen 800mg for pain

	Other Name: Dronabinol
Placebo Comparator: Gestational age up to 10w0d - Placebo Women with gestational age up to 10 weeks 0 days will be randomized to Dronabinol 5mg Cap or placebo	Other: Placebo Subjects randomized to placebo and ibuprofen 800mg for pain

Outcome Measures

Go to

Primary Outcome Measures

1. Maximum self-reported pain score on a numeric rating scale [Time Frame: 24 hours after misoprostol administration]

Women will text responds to surveys within 24 hours after misoprostol administration indicating their maximum self-reported pain using an 11-point numeric rating scale (NRS 0-10) where 0=no pain and 10=worst possible pain.

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: 21 Years to 89 Years (Adult, Older Adult)

Sexes Eligible for Study: Female

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Aged 21 years or older

- Seeking medical abortion
- In good health
- Pregnancy with intrauterine gestational sac up to 10 0/7 weeks, dated by ultrasound
- Able and willing to receive text messages via phone
- Literate in English
- Able and willing to give informed consent and agree to the study terms
- Have assistance at home; no motor vehicle use while taking study medications

Exclusion Criteria:

- Lack of access to cell phone and texting capabilities
- Early pregnancy failure
- Contraindications to the study medications: Dronabinol, Ibuprofen
- Contraindications to medical abortion with Mifepristone or Misoprostol
- History of methadone or heroin use
- Used alcohol in the past 24 hours
- Used marijuana >4 times per week
- Any opioid in the past 30 days
- Using additional pain medications

Contacts and Locations

Go to

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):
NCT03604341

Contacts

Contact: Women's Health Research Unit Confidential Recruitment Line 503-494-3666 whru@ohsu.ec

Sponsors and Collaborators

Oregon Health and Science University

Society of Family Planning

More InformationGo to 

Responsible Party: Katie Alton, MD, Principal Investigator, Oregon Health and Science University

ClinicalTrials.gov Identifier: [NCT03604341](#) [History of Changes](#)

Other Study ID Numbers: OHSU IRB 18195

First Posted: July 27, 2018 [Key Record Dates](#)

Last Update Posted: July 30, 2018

Last Verified: July 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Plan Description: Individual participant data will not be shared with other researchers or used for future research.

Studies a U.S. FDA-regulated Drug Product: Yes

Studies a U.S. FDA-regulated Device Product: No

Product Manufactured in and Exported from the U.S.: Yes

Keywords provided by Katie Alton, MD, Oregon Health and Science University:

Medical Abortion

Pain

Cannabis

Additional relevant MeSH terms:

Dronabinol

Hallucinogens

Physiological Effects of Drugs

Psychotropic Drugs

Analgesics, Non-Narcotic

Analgesics

Sensory System Agents

Peripheral Nervous System Agents

Cannabinoid Receptor Agonists

Cannabinoid Receptor Modulators

Neurotransmitter Agents

Molecular Mechanisms of Pharmacological Action

Hormones

Hormones, Hormone Substitutes, and Hormone Antagonists