Side Effects and Adherence Associated With Doxycycline Use Following Medical Abortion

ClinicalTrials.gov Identifier: NCT01799252

Recruitment Status: Completed
First Posted: February 26, 2013
Last Update Posted: February 3, 2014

Sponsor:
Gynuity Health Projects

Information provided by (Responsible Party):
Gynuity Health Projects

Study Description

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Brief Summary:
The effectiveness of antibiotic treatment at reducing post-abortion infection is unclear. The experiences of women prescribed routine antibiotics after medical abortion is missing from the existing evidence. This study seeks to add to the literature evidence of the side effects associated with antibiotic treatment that women experience and their adherence to prescribed regimens.

Condition or disease
Abortion

Detailed Description:

Medical abortion (MA) consists of administering medication, typically a combination of mifepristone and misoprostol, to induce an abortion without any invasive procedures. Early first trimester MA is effective1, highly acceptable to women, and safe. The risk of infection following medical abortion is small, at less than 1%. In rare circumstances, pelvic infection with clostridia bacteria following medical abortion has resulted in death. Since 2000, when mifepristone was registered in the United States, 8 such deaths have been recorded in the US.

Following the publication of case reports of four clostridium-associated deaths after medical abortion in 2005, the reproductive health community reacted swiftly. Medical abortion protocols were altered in an effort to curb these drastic and rapidly fatal infections. Antibiotic treatment, typically a seven-day course of doxycycline, has become widespread in the United States.

The effectiveness of antibiotic treatment at reducing post-abortion infection is unclear. The experiences of women prescribed routine antibiotics after medical abortion is missing from the existing evidence. This study seeks to add to the literature evidence of the side effects associated with antibiotic treatment that women experience and their adherence to prescribed regimens.

Study Design

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Study Type:	Observational
Actual Enrollment:	582 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	Side Effects and Adherence Associated With Doxycycline Use Following Medical Abortion
Study Start Date:	November 2012
Actual Primary Completion Date:	December 2013
Actual Study Completion Date:	December 2013

Resource links provided by the National Library of Medicine

Drug Information available for: Doxycycline Doxycycline monohydrate Doxycycline hyclate Doxycycline calcium

U.S. FDA Resources

Groups and Cohorts

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Group/Cohort
Doxy Women who are prescribed a seven-day regimen of doxycycline following medical abortion
No Doxy Women who are not prescribed antibiotics following medical abortion

Outcome Measures

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Primary Outcome Measures:

1. Incidence rates of nausea [Time Frame: 7-14 days following medical abortion]

   Compare the incidence rates of nausea between women who are prescribed a seven-day regimen of doxycycline to women who are not prescribed antibiotics following medical abortion

2. adherence [Time Frame: 7-14 days following medical abortion]

   Document the self-reported adherence to antibiotic regimens following medical abortion

Secondary Outcome Measures:

1. Nausea rates [Time Frame: 7-14 days following medical abortion]

   Compare the rates of nausea between women who take at least one doxycycline pill to women who do not take any doxycycline following medical abortion

2. Non-nausea side effects [Time Frame: 7-14 days following medical abortion]

   Compare the rates of other (non-nausea) side effects between women who are prescribed a seven-day regimen of doxycycline to women who are not prescribed antibiotics following medical abortion

3. Additional medications [Time Frame: 7-14 days following medical abortion]

   Compare the use of additional medication to treat side effects between women who take antibiotics and women who do not take antibiotics following medical abortion

4. Cost [Time Frame: at time of filling prescription]

   Document the cost to women of antibiotics regimens following medical abortion

Eligibility Criteria

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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:	Child, Adult, Senior
Sexes Eligible for Study:	Female
Accepts Healthy Volunteers:	Yes
Sampling Method:	Non-Probability Sample

Study Population

This study will enroll 610 women. Women will be recruited from 5 clinics and will self-administer, or if necessary, a study coordinator will administer, a computer-based questionnaire 7-14 days following administration of mifepristone.

Criteria

Inclusion Criteria:

- Women who are having MA at the study clinic and are willing to complete a self-administered, computer-based questionnaire 7-14 days after taking mifepristone
- Women who can read English or Spanish
- In the doxycycline arm: Women who have been prescribed doxycycline

Exclusion Criteria:

- Women who were treated with antibiotics for a medical condition unrelated to their medical abortion between the initial visit and follow-up appointment
- Women who have previously enrolled in this study

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): ***NCT01799252***

Locations

United States, Georgia

Feminist Women's Health Center
Atlanta, Georgia, United States, 30329

United States, Illinois

Family Planning Associates
Chicago, Illinois, United States, 60630

United States, Michigan

Planned Parenthood Mid and South Michigan
Ann Arbor, Michigan, United States, 48104

United States, Minnesota

Planned Parenthood MN, ND, SD
St. Paul, Minnesota, United States, 55114

United States, New York

Family Practice and Sidney Hillman Family Practice at the Institute for Family Health
New York, New York, United States, 10003

NYU/Bellevue Hospital Center, Women's Health Center
New York, New York, United States, 10016

United States, Washington

Cedar River Clinic
Renton, Washington, United States, 98057

Sponsors and Collaborators

Gynuity Health Projects

Investigators

Principal Investigator: Beverly Winikoff, MD, MPH Gynuity Health Projects

More Information

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Additional Information:

Sponsor website EXIT

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Frye LJ, Chong E, Winikoff B; NCT01799252 Trial Investigators. What happens when we routinely give doxycycline to medical abortion patients? Contraception. 2015 Jan;91(1):19-24. doi: 10.1016/j.contraception.2014.09.001. Epub 2014 Sep 15.

Responsible Party:	Gynuity Health Projects
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Keywords provided by Gynuity Health Projects:
medical abortion
doxycycline
antibiotics
adherence
nausea

Additional relevant MeSH terms:

Doxycycline	Antimalarials
Anti-Bacterial Agents	Antiprotozoal Agents
Anti-Infective Agents	Antiparasitic Agents