A Trial of Digoxin Before Second-Trimester Abortion

ClinicalTrials.gov Identifier: NCT01047748

Recruitment Status : Completed
First Posted : January 13, 2010
Last Update Posted : May 1, 2013

Sponsor:
White, Katharine O'Connell, M.D., M.P.H.

Collaborator:
Society of Family Planning

Information provided by (Responsible Party):
White, Katharine O'Connell, M.D., M.P.H.

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:
The purpose of our study is to determine the optimum route for the injection of digoxin prior to second-trimester surgical abortion.

Condition or disease	Intervention/treatment	Phase

Induced Abortion	Drug: intra-fetal digoxin injection Drug: intra-amniotic digoxin injection	Not Applicable

Detailed Description:

Of the 1.2 million abortions each year in the U.S., approximately 12% take place in the second trimester of pregnancy. The preferred technique for second-trimester pregnancy termination is dilation and evacuation, or D&E. In 2006, 144,000 D&Es were performed in the U.S. Clinicians often achieve preoperative fetal asystole by a maternal transabdominal injection of digoxin. Prior to D&E, providers use digoxin to induce fetal death 1) for providers' preference to facilitate surgical delivery of the fetus, and/or 2) for patients who express a desire for fetal death prior to the abortion.

The use of digoxin to achieve preoperative fetal asystole is widespread, yet there are no evidence-based standards for how to best achieve fetal asystole prior to D&E. Digoxin has been administered by intracardiac, intrathoracic, intrafetal and intra-amniotic routes, with doses varying from 0.25 to 2mg. Clinicians who use digoxin usually inject it one to two days before the D&E. Only one study has assessed the effectiveness of digoxin at varying dosages ; this was a retrospective and nonrandomized analysis. Published failure rates are based on small numbers of patients and are therefore imprecise. Intrafetal digoxin injection may be more effective, but is a technically more difficult procedure than intra-amniotic injection. The pharmacodynamics of digoxin when used for feticide are also unknown. The objective of this study is to determine the optimum route for digoxin injection (intrafetal or intra-amniotic) that will maximize patient safety while maintaining effectiveness.

Study Design

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Study Type :

Interventional (Clinical Trial)

Actual Enrollment :

272 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Masking:

None (Open Label)

Official Title:

A Randomized Clinical Trial of Intra-fetal Versus Intra-amniotic Digoxin Prior to Second-Trimester Pregnancy Termination

Study Start Date :

January 2011

Actual Primary Completion Date :

January 2013

Actual Study Completion Date :

January 2013

Resource links provided by the National Library of Medicine

Drug Information available for: Digoxin

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Active Comparator: intra-fetal injection Subjects will receive an intra-fetal digoxin injection one day prior to their second-trimester surgical abortion	Drug: intra-fetal digoxin injection Single transabdominal injection of digoxin 1 mg into the fetus Other Name: Lanoxin
Active Comparator: intra-amniotic injection Subjects will receive an intra-amniotic digoxin injection one day prior to their second-trimester surgical abortion	Drug: intra-amniotic digoxin injection Single transabdominal injection of digoxin 1 mg into the amniotic fluid Other Name: Lanoxin

Outcome Measures

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Primary Outcome Measures :

1. difference in fetal asystole rates between groups [Time Frame: one day]

Secondary Outcome Measures :

1. digoxin-related side effects [Time Frame: one day]
2. differences in surgical procedure between groups [Time Frame: one day]

3. subject satisfaction [Time Frame: one day]
4. serum digoxin levels in study subgroup [Time Frame: one day]

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:

18 Years to 55 Years (Adult)

Sexes Eligible for Study:

Female

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- at least 18 years old
- English or Spanish speaking
- be able to give informed consent
- documented fetal cardiac activity.

Exclusion Criteria:

- significant medical illness or cardiovascular disease
- current use of cardiac or antihypertensive medications
- cardiac arrhythmia on preoperative EKG
- multiple gestation
- morbid obesity (BMI greater than 40)
- known digoxin allergy

Contacts and Locations

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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): ***NCT01047748***

Locations

United States, California

Planned Parenthood Los Angeles - Bixby Health Center
Los Angeles, California, United States, 90033

Sponsors and Collaborators

White, Katharine O'Connell, M.D., M.P.H.

Society of Family Planning

Investigators

Principal Investigator: Katharine O White, MD, MPH Physicians for Reproductive Choice and Health

More Information

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Publications:

Jackson RA, Teplin VL, Drey EA, Thomas LJ, Darney PD. Digoxin to facilitate late second-trimester abortion: a randomized, masked, placebo-controlled trial. Obstet Gynecol. 2001 Mar;97(3):471-6.

Molaei M, Jones HE, Weiselberg T, McManama M, Bassell J, Westhoff CL. Effectiveness and safety of digoxin to induce fetal demise prior to second-trimester abortion. Contraception. 2008 Mar;77(3):223-5. doi: 10.1016/j.contraception.2007.10.011. Epub 2008 Jan 22.

Drey EA, Thomas LJ, Benowitz NL, Goldschlager N, Darney PD. Safety of intra-amniotic digoxin administration before late second-trimester abortion by dilation and evacuation. Am J Obstet Gynecol. 2000 May;182(5):1063-6.

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

White KO, Nucatola DL, Westhoff C. Intra-fetal Compared With Intra-amniotic Digoxin Before Dilation and Evacuation: A Randomized Controlled Trial. Obstet Gynecol. 2016 Nov;128(5):1071-1076.

Responsible Party:

White, Katharine O'Connell, M.D., M.P.H.

ClinicalTrials.gov Identifier:

NCT01047748 History of Changes

Other Study ID Numbers:

20082058

First Posted:

January 13, 2010 Key Record Dates

Last Update Posted:

May 1, 2013

Last Verified:

April 2013

Keywords provided by White, Katharine O'Connell, M.D., M.P.H.:

abortion

Additional relevant MeSH terms:

Digoxin
Anti-Arrhythmia Agents
Cardiotonic Agents
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Protective Agents
Physiological Effects of Drugs