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Studying the feasibility and effectiveness of self-managed medication abortion

Submission date
31/07/2019

Recruitment status
No longer recruiting

Registration date
15/08/2019

Overall study status
Completed

Last Edited
07/07/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Around the world, people face myriad structural barriers and legal restrictions that prevent access to high-quality abortion services in both the public and private sectors. Increasingly, those in need of abortion care who cannot access facility-based services are obtaining abortifacient medicines through informal routes including online services, pharmacies, hotlines, drug sellers, and public health activist groups. Globally, more than 40 grassroots organizations provide people with evidence-based counseling and support through the medication abortion process outside of the formal health care system. This non-clinic based model of abortion care has come to be known as the “accompaniment model”. However, there is a lack of peer-reviewed evidence in the scientific literature about the safety and effectiveness of self-managed medication abortion administered completely outside of the formal healthcare system.

Who can participate?
People at least 13 years old who contact the hotline/accompaniment group seeking information about induced abortion for their own pregnancy, who are able to speak the local language, grant informed consent, have no contraindications to medication abortion, do not have signs of an ectopic pregnancy, are not currently bleeding and are starting a new medication abortion process are eligible to participate.

What does the study involve?
The study involves interview-administered questionnaires about participant experiences regarding their medication abortion process. Participants complete a baseline questionnaire at the time of enrolment, and are followed up at 7 days and 21 days after the date they take their first dose of medication abortion pills. Participants who do not have a complete abortion at 21 days are eligible for continued follow-up through 6 weeks after starting their medication abortion process.

What are the possible benefits and risks of participating?
There is no direct benefit to participating. As this is an observational study, the main risks that participants face are feeling uncomfortable because of sensitive questions, or loss of confidentiality if their conversation with the interviewer is overheard. Participants are informed that they can skip any question they do not wish to answer, and to ensure that they are in a

private location without danger of being overheard prior to commencing any follow-up questionnaires.

Where is the study run from?
Participants will be recruited from Argentina, a country in West Africa, and a country in Southeast Asia.

When is the study starting and how long is it expected to run for?
Recruitment for the study commences on July 31, 2019, and will end on March 31, 2021. Recruitment will end early if the sample size is met.

Who is funding the study?
This study is funded by the David and Lucile Packard Foundation.

Who is the main contact?
Dr. Heidi Moseson
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SAFE032019

Study information

Scientific Title
Studying Accompaniment model Feasibility and Effectiveness: a prospective, non-inferiority study of the effectiveness of self-managed medication abortion

Acronym
SAFE

Study objectives
Self-managed medication abortion with support from an accompaniment organization is no more than 5% less effective than medication abortion administered in a clinical setting. The medication regimens to be evaluated include misoprostol alone and misoprostol in combination with mifepristone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 07/03/2019, the Allendale Investigational Review Board (30 Neck Road Old Lyme , CT 06371; 860-434-5872; 860-434-5892; Rta1ali1@aol.com), ref: SAFE032019.
2. Approved 25/03/2019, Huesped Foundation Bioethics Committee (Gianantonio, Carlos Dr. (former Pje. Peluffo) 3932 (C1202ABB) Autonomous City of Buenos Aires, Argentina; (5411) 4981 7777; fhuesped@huesped.org.ar).

Study design
Prospective, observational dynamic cohort study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Self-managed medication abortion

Interventions
This study is a prospective, observational dynamic cohort study of people who contact safe abortion hotlines/accompaniment groups in Argentina, a country in Southeast Asia, and a

country in West Africa for information and support with self-managing an abortion with medication. Medication regimens used are either misoprostol alone or misoprostol in combination with mifepristone. Any person over the age of 13 that is considered eligible for self-managed medication abortion by the hotline, does not have signs of an ectopic pregnancy, is not currently bleeding, and is capable of granting informed consent will be eligible for this study. Participants who contact the hotline are assessed for eligibility by hotline/accompaniment group staff. At the end of the counselling session, eligible participants are invited to participate in the study. The counselling session prior to enrolment varies by organization, but all provide step-by-step protocols for how to use medication to safely induce abortion based on current World Health Organization (WHO) protocols. In addition to information about medication abortion protocols, models may also provide information on how the drugs function, how to manage pain, how to recognize complication signs, potential interactions with medical personnel in case of emergency treatment seeking, how to confirm abortion completion, what to expect after the abortion, and prevention of future unwanted pregnancy. Participants who consent are enrolled in the study and complete an interview-administered baseline questionnaire.

Enrolled participants are followed prospectively to assess their abortion outcome and experiences. Interview-administered questionnaires will be completed at enrollment (baseline), seven days after starting their medication abortion process (1st follow-up), and 21 days after starting their medication abortion process (2nd follow-up) via phone call or secure messaging service. Participants whose abortion status is incomplete, unknown, or failed at 21 days will receive an additional follow-up at 28 days after starting their medication process (3rd follow-up). In the event that the outcome of abortion cannot be determined at the additional 3rd follow-up, study coordinators will contact participants at an additional follow-up two-weeks later (six weeks after taking the pills) to record their final abortion outcome. The maximum follow-up time is 6 weeks after participants report first taking medications for abortion.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Misoprostol, mifepristone

Primary outcome measure
The proportion of participants with a complete abortion without the need for surgical evacuation is determined by the proportion of participants who report “yes” to the question “Do you feel that your abortion process is complete?” and who do not report any surgical intervention at first follow-up, second follow-up, and study end.

Secondary outcome measures
1. Signs of complication are determined using participant self-report of selected signs of complication at intervention at each follow-up.
2. Time to expulsion is determined using participant self-report of time from first medication dose to expulsion at each follow-up.
3. Ongoing pregnancy is determined using participant self-report of ongoing pregnancy at each follow-up.
4. Medical treatment/surgical intervention are determined using participant self-report at each follow-up.

5. The proportion of participants with complete abortion overall (with or without surgical evacuation) is determined using participant self-report at each follow-up.

Overall study start date
01/10/2018

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Contacted the accompaniment group seeking information about induced abortion for their own pregnancy
2. At least 13 years of age
3. Able to give informed consent
4. Able to speak the local language
5. Meets accompaniment group eligibility criteria for starting medication abortion process (i.e. no known contraindications to medication abortion)
6. Starting a new medication abortion process

Participant type(s)
Other

Age group
Mixed

Sex
Female

Target number of participants
1300

Total final enrolment
1352

Key exclusion criteria
1. Are experiencing ongoing symptoms (bleeding, cramping) from a previous abortion attempt prior to study enrollment
2. Have a known ectopic pregnancy or symptoms of an ectopic pregnancy
3. Do not want to share their contact information with study staff
4. Do not want to be contacted again by the hotline or by study staff
5. Are not willing to comply with study procedures
6. Cannot access a phone and private location to answer questions during follow-up

Date of first enrolment
31/07/2019

Date of final enrolment
28/02/2021

Locations

Countries of recruitment
Argentina

Study participating centre
Names of organizations withheld to protect privacy
Argentina
B1675

Sponsor information

Organisation
Ibis Reproductive Health

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Sponsor type
Research organisation

Website
https://ibisreproductivehealth.org/

ROR
https://ror.org/01va7e105

Funder(s)

Funder type
Charity

Funder Name
David and Lucile Packard Foundation

Alternative Name(s)

David & Lucile Packard Foundation, The David and Lucile Packard Foundation, Packard Foundation, The Packard Foundation, The David & Lucile Packard Foundation, DLPF, PF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal, submission to sexual and reproductive health-focused academic conferences, and via research briefs, webinars, and other targeted dissemination activities.

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	feasibility results from pilot study	27/10/2020	29/10/2020	Yes	No
Protocol article	main study protocol	19/11/2020	18/01/2021	Yes	No
Results article		18/11/2021	22/11/2021	Yes	No
Results article		06/07/2023	07/07/2023	Yes	No