Permission to Take Part in a Human Research Study

Title of Research Study: Continuation Rates of Self-administered Subcutaneous Depot Medroxyprogesterone Acetate and Provider-administered Intramuscular Depot Medroxyprogesterone Acetate in Patients Seeking Post-abortion Contraception

Principal Investigator: Dr. Ashley Turner

Supported By: This research is supported by the Society of Family Planning.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you indicated that you would like to use Depo-Provera for birth control after your abortion.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- You do not have to answer any question you do not want to answer.

Why is this research being done?
At this clinic, patients who want Depo-provera for birth control after their abortion usually get a shot given in their muscle (intramuscular Depo-provera) from a healthcare provider. There is also a type of Depo-provera that patients can give to themselves under their skin (subcutaneous Depo-provera), which is just as safe and effective. The purpose of the research study is to learn more about patients' experiences with giving the Depo-provera shot to themselves compared with getting the Depo-provera shot from a healthcare provider after an abortion.

How long will the research last and what will I need to do?
We expect that you will be in this research study for 6 months.

You will choose to get Depo-provera after your abortion either from a healthcare provider in the clinic or give it to yourself. You will get a prescription for a year's worth of additional doses to get at a clinic of your choice or to give to yourself and will fill out surveys about your experience using Depo-provera over the next 6 months.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?
Getting Depo-provera for birth control is very safe for most women. Some women have side effects from Depo-provera.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, if you choose to give yourself Depo-provera possible benefits include receiving education on how to give yourself injections and getting a type of birth control that may be more convenient for you to use.

If you choose to get Depo-provera shots from a healthcare provider, there are no benefits to you from your taking part in this research.

We cannot promise any benefits to others from your taking part in this research. Possible benefits to others include helping expand access to another form of birth control that is not as commonly available.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

You may choose to receive the Depo-provera shot in your muscle from a healthcare provider at this clinic without participating in this research study. This is the option that would normally be offered to a patient who wanted Depo-provera for birth control and was not participating in research.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team, including the Principal Investigator Dr. Ashley Turner at 312-926-8678 or Dr. Erica Bishop at 312-926-8678.

- This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irbcompliance@northwestern.edu if:
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect that 586 people who come to the clinic will be in this research study.

What happens if I say "Yes, I want to be in this research"?

If you decide to participate in this research study, you will choose to either get a Depo-provera shot in your muscle from a health care provider or to give a Depo-provera shot to yourself under your skin after having an abortion. You will receive a prescription for a year's worth of Depo-provera so that you can either give it to yourself or get it at a clinic that you choose every 3 months following your abortion. You will receive a calendar telling you when you are due for your next shots of Depo-provera. You will also receive a reminder before each Depo-provera shot is due. This reminder will be sent via a secure text messaging application. If you prefer, the research team can contact you via phone, email, or mail

If you choose to give Depo-provera to yourself, a member of the research team will teach you how to give yourself the Depo-provera shot. You will also receive a sharps box where you can safely store used needles.

Getting the Depo-provera shot in your muscle from a healthcare provider and getting the Depo-provera shot under your skin are considered standard of care, because both medications are approved by the United States Food and Drug Administration (US FDA), are considered safe, and are not considered experimental medications. The FDA has not approved the Depo-provera shot given under the skin for patients to give to themselves. However, the Centers for Disease Control (CDC) recommends that patients be allowed to give themselves the Depo-provera shot under their skin.

The study will start today before your abortion and will continue for 6 months after your abortion. You will be asked to complete 3 surveys, including one today before your abortion and then 3 and 6 months from now after your Depo-provera shots are due. The surveys will be confidential, secure, and will not contain your personal identification. The surveys range from 18-30 questions and are estimated to take approximately 5-15 minutes to complete. We estimate that the total amount of time spent on taking all the surveys will be about 40 minutes. You will interact with members of the research team and interaction will be primarily via secure text messaging application. If you prefer, the research team can contact you via phone, email, or mail. The first survey will take place in the clinic and the follow up surveys will be sent to you via a secure link in a text message.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can stop contacting you for follow up surveys. The researchers will ask you if information already collected from you can be used.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Detailed Risks: Is there any way being in this study could be bad for me?

- There are no legal risks
- There are no group or community risks

Physical Risks:

Some women have side effects from Depo-provera including heavy or irregular periods, increased menstrual cramps, abdominal pain, back pain, leg cramps, joint pain, breast pain, weight gain, acne, fatigue, dizziness, difficulty sleeping, hot flashes, headache, hair loss, nausea, bloating, anxiety, irritability, depression, decreased sex drive, difficulty becoming pregnant after stopping Depo-provera, vaginal infection or discharge, bladder infection, skin rash, and discomfort or irritation at the site where you get the shot

Depo-provera should not be used in women who have blood clots, liver disease, or breast cancer, have had an allergic reaction to Depo-provera in the past, or have irregular vaginal bleeding that does not have an explanation. You will only be able to participate in this research study if the health care providers at this clinic have already determined that Depo-provera is a safe form of birth control for you, according to the guidelines on birth control from the Centers for Disease Control (CDC). This will decrease physical risks to you as a research study participant.

Depo-provera may cause a significant decrease in your bone density. Bone loss increases the longer you use Depo-provera. You might not regain the bone that you lose while using Depo-provera. Depo-provera is not recommended to be used longer than 2 years, unless there are not other options that are appropriate for you.

Depo-provera prevents pregnancy, but it does not protect you from sexually transmitted infections (STIs).

These risks are not unique to participating in the research study, meaning that these risks are present for anyone who gets the Depo-provera shot regardless of whether they are participating in a research study or not.

Psychological and Social Risks:
Some questions in the research surveys may make you uncomfortable. You are not required to answer any survey questions that you do not wish to and you may stop taking part in the research study at any time without penalty.

Economic Risks:
Taking part in this research study may lead to added costs to you. For more details see the section **"Will it cost me anything to participate in this research study?"**

Confidentiality Risks:
This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

Will it cost me anything to participate in this research study?

Taking part in this research study may lead to added costs to you. Your initial dose of Depo-provera will be provided in the clinic at no cost to you. You will be given a prescription for the following doses of Depo-provera. You and your insurance company will be charged for the cost of the prescription that you would ordinarily be responsible to pay. If you choose to receive the Depo-provera shot in your muscle given to you by a health care provider you and your insurance company will also be charged for the cost of the clinic visit to receive the medication

at the clinic of your choice. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include:

If you choose to give yourself the Depo-provera shot under your skin, this may be more convenient for you and make it easier for you to get your follow up doses. You will also receive education on how to give yourself injections. This education may be useful or valuable to you.

If you choose to receive the Depo-provera shot in your muscle, given to you by a health care provider, there will be no direct benefit to you, because this is how patients usually get Depo-provera at this clinic.

Participating in this research study may help other patients. While there has been research on patients using subcutaneous Depo-provera (the type of Depo-provera shot that you can give to yourself under your skin) it has not been studied in patients who want birth control after an abortion. Information that we gather from this research study may help health care workers provide better counseling and options to patients who want Depo-provera for birth control after an abortion.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include deciding to continue your pregnancy instead of having an abortion or having a serious allergic reaction to Depo-provera.

What else do I need to know?

If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury. The researchers will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you for your time and effort for each segment of the study that you complete. We will pay you $20 for completing the initial study visit and survey and $15 for each of the two follow up surveys. If you complete the entire research study you will be paid up to $50.

You will be issued a Stored Value Card (VISA), which is a type of bank debit card with a specific dollar value programmed into it. Once a visit that qualifies for compensation is completed, funds will be approved and loaded onto your card.

You will need to set a PIN to use the card at an ATM. Using the PNC automated service number and Account Access Code provided on the card, follow the prompts to establish a PIN. You may also call this number to obtain the current balance on the card and to verify your activity. A fee will be charged to speak to a live operator. This information can also be checked online at pncprepaidcard.com. Please note that neither PNC nor Northwestern can obtain the PIN if forgotten.

If the card is used at a PNC ATM, there is no fee; however, there will be a $2.50 charge for non-PNC ATM withdrawals. One card will be issued for the duration of your participation. If your card is lost or stolen, please call the study team on the contact information provided on this consent document.

Please be advised: You will incur a fee if the card is not used in 6 months and a monthly fee for each additional month of non-use. However, as long as there is activity (funds are added or card is used), on the card within 6 months, the month period will reset and no monthly fee will be assessed. If the card is used at a restaurant, there will be a 20% "hold" above the tab amount. The card will be declined if used at a gas pump. Rather, the card must be physically presented to the gas station attendant.

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Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may keep my contact information in order to contact me in the future to see whether I am interested in participating in other research by the Principal Investigator.

Consent to Participate in Research

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent