

EFFECT OF TIMING OF POSTPARTUM DEPOT MEDROXYPROGESTERONE ACETATE  
ADMINISTRATION ON BREASTFEEDING CONTINUATION, CONTRACEPTIVE  
USAGE, AND POSTPARTUM DEPRESSION: A RANDOMIZED TRIAL

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## ABSTRACT

In the United States, depot medroxyprogesterone acetate (DMPA) is frequently administered prior to hospital discharge with the belief that women who delay initiation of DMPA may face higher risk of unintended pregnancy and that administration postpartum has little to no negative effect on breastfeeding. Administering DMPA to breastfeeding women has not been widely questioned because the limited existing studies do not show any adverse impact of DMPA on breastfeeding. However, these studies used inappropriate control groups and did not control for prior lactation experience.(1-3) We recently conducted a randomized controlled trial (RCT) which found that significantly fewer women who underwent immediate postplacental levonorgestrel-releasing IUD (LNG-IUD) placement continued to breastfeed at 6 months compared to those who underwent insertion at 6-8 weeks postpartum.(4) Since systemic levels of progestins are much less with the LNG-IUD compared to DMPA, we became concerned about potential effects of administering DMPA immediately postpartum.

We therefore propose to enroll 184 women who plan to breastfeed and use DMPA postpartum in a RCT to investigate whether the timing of postpartum administration of DMPA (prior to hospital discharge vs. 4-6 weeks postpartum) affects the duration or exclusivity of breastfeeding among women who plan to breastfeed their infants. Secondary outcomes will include rates of use of highly effective contraception (defined as DMPA, IUD, implant, sterilization, or lactational amenorrhea) and postpartum depression. Outcomes will be assessed by phone at 2, 4, 6, 8, 12, 16, 20, 24, and 28 weeks postpartum.

## 1. SPECIFIC AIMS AND HYPOTHESES

### SPECIFIC AIMS:

To compare the effect of administering postpartum intramuscular (IM) depot medroxyprogesterone acetate (DMPA) prior to hospital discharge compared to 4-6 weeks after delivery on: 1) exclusivity and duration of breastfeeding; 2) use of highly effective contraception; and 3) postpartum depression

### HYPOTHESES:

1. Women who receive DMPA 4-6 weeks after delivery will be more likely than women who receive DMPA prior to hospital discharge to exclusively breastfeed for 6 months.
2. Women who receive DMPA 4-6 weeks after delivery will be as likely as women who receive DMPA prior to hospital discharge to use highly effective contraception (i.e. DMPA, intrauterine device (IUD), implant, sterilization, or lactational amenorrhea) at 6 months after delivery.
3. Women who receive DMPA 4-6 weeks after delivery will be no more likely than women who receive DMPA prior to hospital discharge to develop postpartum depression as measured by the Edinburgh Postnatal Depression Scale.(5)

## 2. PREVIOUS RESEARCH

Postpartum contraception is important because unintended pregnancy rates range from 10%-20% in the first year postpartum.(6, 7) Lactational amenorrhea (LAM) can be effective contraception for up to 6 months.(8) However, many US women stop breastfeeding soon after delivery. By two weeks postpartum, an estimated 59% of US women started supplementation (2) and 37% of women stopped breastfeeding.(9) If sexually active and not using contraception, such women are at risk for unintended pregnancy.

Postpartum visits in the US generally occur 4-6 weeks after delivery.(10) Although 85% of women return for postpartum visits,(11) approximately half of women initiate sexual activity before six weeks postpartum and 82% are sexually active by 12 weeks postpartum.(12) Since ovulation can occur by 4 weeks postpartum in non-breastfeeding women,(13) experts recommend that women who are not exclusively breastfeeding should initiate contraception by 3 weeks postpartum.(14) Some also recommend that the postpartum visit should occur by 2-4 weeks postpartum in order to address contraception, breastfeeding, and postpartum depression,(14, 15) since postpartum depression affects 10%-15% of mothers (16) and can be associated with poor maternal-infant interactions and attachment.(17) Studies of the association of depression and breastfeeding discontinuation are conflicting.(18-20) One study of norethisterone enanthate given within 48 hours of delivery found an increased risk of postpartum depression,(21) but no studies have examined the effect of timing of DMPA administration on postpartum depression, contraceptive use, or breastfeeding.

Breastfeeding has many benefits, including immunologic protection and nutrition for the infant, more rapid uterine involution, decreased postpartum bleeding, and improved infant-bonding.(22) Exclusive breastfeeding for at least six months is recommended by the American College of Obstetricians and Gynecologists and the World Health Organization.(22, 23) However, only 41% of children in the National Immunization Survey were breastfed for 6 months.(24)

Because progesterone withdrawal may be the stimulus that initiates lactogenesis II, administration of progestin-only methods shortly after delivery could possibly inhibit or alter lactation.(25) Theoretically, a delay in the onset of lactation could lead to early formula supplementation and reduced exclusivity of breastfeeding. Prior studies of progestin-only methods have not found detrimental effects on infant growth or development (26, 27) or adverse impact on breastfeeding.(1-3) Accordingly, the US Medical Eligibility Criteria for Contraceptive Use (MEC) considers DMPA administration <4 weeks postpartum to be category 2, meaning the advantages generally outweigh the risks.(28) However, none of the studies reviewed by the authors of the US MEC were randomized trials, and thus may be subject to residual confounding, since women who choose DMPA differ from women who choose non-hormonal contraception, so use of the latter group as a comparator is incorrect. Also, some studies did not investigate timing of DMPA initiation (1, 2) or long-term DMPA continuation rates.(2) Most importantly, we recently found a significant difference in breastfeeding continuation in a randomized trial comparing immediate postplacental LNG-IUD insertion to delayed insertion at 6-8 weeks after vaginal delivery. In our study, only 9% of women who initiated breastfeeding and received a postplacental LNG-IUD were breastfeeding at 6 months compared to 41% of women who received an IUD at 6-8 weeks ( $p=0.006$ ).(4)

Since serum progestin levels with the LNG-IUD are much lower than with DMPA and given the limitations of previous studies of DMPA use by breastfeeding women, it is vital that we rigorously evaluate the effects of timing of postpartum DMPA administration on breastfeeding continuation, use of effective contraception, and postpartum depression.

### **3. RATIONALE**

DMPA is frequently given prior to hospital discharge in the US due to concerns that women will not follow-up for postpartum contraception. Given the severe limitations of currently published literature on breastfeeding following DMPA administration, and the recent study suggesting that immediate postplacental LNG-IUD insertion could negatively impact breastfeeding continuation, a properly performed randomized study to evaluate the use of immediate or delayed postpartum DMPA administration is needed. This study will be valuable in helping clinicians provide accurate advice to patients about potential effects of early DMPA administration on breastfeeding continuation, contraceptive use, and postpartum depression.

#### **4. RELEVANCE TO SFP**

This study is a high-priority topic for SFP since it focuses on the effects of immediate postpartum use of progestin-only contraception on breastfeeding performance.

#### **5. RESEARCH DESIGN AND METHODS**

**5.1 Overview:** We will enroll 184 pregnant subjects who plan to breastfeed and use DMPA for postpartum contraception. Subjects will be randomized to IM DMPA administration prior to hospital discharge or at 4-6 weeks after delivery (in the office of their primary obstetrician or midwife). Follow-up phone calls will be conducted at 2, 4, 6, 8, 12, 16, 20, 24, and 28 weeks after delivery. We will assess duration of exclusive and total breastfeeding, contraceptive use at 3 and 6 months, and rates of postpartum depression.

##### **5.2 Criteria for selection of subjects**

Inclusion criteria:

- 1.) Age  $\geq$  18 years old at time of enrollment
- 2.) Gestational age of 24 0/7 weeks or higher, or postpartum, and have not already received DMPA
- 3.) Planning to deliver at Magee-Womens Hospital and to breastfeed
- 4.) Plans to use DMPA for postpartum contraception for at least 6 months, or plans to use DMPA for postpartum contraception until starting a more effective form of contraception such as an intrauterine device, contraceptive implant, or sterilization
- 5.) Willing and able to provide informed consent in English and to comply with study protocol

Exclusion criteria:

- 1.) Intolerance of irregular vaginal bleeding
- 2.) Severe coagulation disorder
- 3.) Severe liver disease (LFTs  $>2x$  upper limits of normal at time of randomization)
- 4.) Contraindications to breastfeeding: maternal HIV infection; active herpes simplex with breast lesions; active varicella; active, untreated tuberculosis; antineoplastic, thyrotoxic, or immunosuppressive medications; concern that the infant may have galactosemia
- 5.) History of breast cancer, reduction or augmentation surgery
- 6.) History of severe clinical depression
- 7.) Multiple gestation

**5.3 Subject recruitment:** Potential subjects will be identified during prenatal care by their primary obstetrician, midwife after receiving routine counseling for postpartum contraception, or on the

postpartum floor. If a woman is interested in the study, the primary obstetrician, postpartum nurse, or midwife will call the Center for Family Planning Research (CFPR). The potential subject will be scheduled for a visit in CFPR for screening and enrollment, or seen in-person on the postpartum unit.. Each subject will receive routine care from her primary obstetrician or midwife throughout her pregnancy, during delivery, and postpartum except as discussed per the research design.

**5.4 Screening and enrollment:** Pregnant women will be screened to ensure they meet all entry criteria.

Data collection on enrollment will include:

- a. Demographic information
- b. Medical history (including height and prepregnancy weight), obstetric and gynecologic history (including breastfeeding experience and contraceptive history)
- c. Psychiatric history (including depression, anxiety and substance use)
- d. Breastfeeding intentions as measured by the Infant Feeding Intentions Scale (29)
- e. Psychosocial factors that can affect breastfeeding discontinuation, such as family/friend support for breastfeeding, plans for return to work/school, and confidence in ability to breastfeed (18)

**5.5 Subject allocation:** An independent individual will prepare allocation packets using a computer generated random number table. These packets will be placed in a sequentially numbered opaque tamper-resistant sealed envelope. Equal numbers of subjects will be randomly allocated to the following groups:

- 1.) Group 1. DMPA administration prior to hospital discharge.
- 2.) Group 2. DMPA administration at 4-6 weeks after delivery.

**5.6 Admission for delivery:** Research staff will check the hospital census daily for any study subjects. Obstetricians and midwives will be asked to contact the investigators after a subject's delivery and prior to hospital discharge. For women who will enroll in the study postpartum, a member of the postpartum staff or the medical team taking care of the patient will notify the patient of the available study. If the patient is interested in discussing the study with a member of the study team, the postpartum staff member will contact the research office. The verbal permission will be documented by the referring staff member, and filed in the research chart. A member of the research team will proceed with obtaining informed consent, and complete the visit on the postpartum unit. Day of delivery will be considered Day 0. Prior to hospital discharge (and ideally on postpartum day 1), subjects will be interviewed by research staff to assess whether she has initiated breastfeeding and remains eligible for the study. If she has not attempted breastfeeding at least once, does not plan to breastfeed, and/or no longer plans on using DMPA postpartum for contraception, she will be excluded from the study. All other exclusion criteria will again be reviewed to ensure that the subject has not developed any contraindications to DMPA administration

or breastfeeding. If entry criteria are satisfied, the next lowest numbered randomization packet will be opened to determine randomization allocation. All subjects will be informed that pelvic rest is advised for 4-6 weeks.

- 1.) Group 1: An investigator will order DMPA to be administered prior to hospital discharge. The subject's subsequent DMPA injection will be due 11-13 weeks after the injection. The subject will follow up with her primary obstetrician or midwife for further DMPA administrations.
- 2.) Group 2: The subject will be asked to follow up with her primary obstetrician or midwife at 4-6 weeks after delivery for DMPA administration or to start a more effective form of contraception such as an IUD or implant, or to be scheduled for sterilization. She will be instructed to use condoms until her follow-up visit if she is not abstinent. She will also be instructed on emergency contraception use.

A questionnaire about breastfeeding intentions and whether lactogenesis II has occurred (i.e. the mother's "milk has come in") will be administered prior to discharge. Information about the delivery and postpartum course will be collected, including type of delivery, birth weight, gestational age, Apgar scores, and subject's height and weight at time of delivery. The subject's primary obstetrician or midwife will be notified of plans for administering the woman's next dose of DMPA. Routine postpartum care (including referrals for lactation consultation or behavioral health services) will be provided by the subject's primary obstetrician or midwife. Any subject who decides to use an alternate form of contraception after randomization will be followed per protocol. The 2-week follow-up phone contact will be scheduled prior to discharge.

**5.7 Follow-up contacts:** Subjects will be contacted by phone at the following time points:

1) Week 2: day 12-19 (goal day 14)	6) Week 16: day 108-118 (goal day 112)
2) Week 4: day 26-33 (goal day 28)	7) Week 20: day 136-146 (goal day 140)
3) Week 6: day 40-47 (goal day 42)	8) Week 24: day 164-174 (goal day 168)
4) Week 8: day 54-61 (goal day 56)	9) Week 28: day 192-202 (goal day 196)
5) Week 12: day 80-90 (goal day 84)	

#### *OUTCOME ASSESSMENTS*

- A questionnaire about breastfeeding (including psychosocial factors related to breastfeeding and introduction of alternatives to breastmilk) and contraceptive use will be administered at each contact. Timing of lactogenesis II will be assessed at Week 2 unless it occurred prior to discharge. Timing of postpartum sexual activity initiation will also be assessed. At any point when the subject reports cessation of breastfeeding, a questionnaire will be administered to assess reasons for discontinuation.

- The Edinburgh Postnatal Depression Scale (EPDS) will be administered at each contact as a screening tool for postpartum depression.(5) If a subject scores  $\geq 12$  on the EDPS, she will be referred to the Magee Behavioral Health clinic or to a behavioral health clinic of her choice and her primary obstetrician or midwife will be notified.
- Subjects will be asked if they had any visits with their primary obstetrician, midwife, or any other provider since the last contact. Records will be requested from all reported visits.
- The next telephone contact will be scheduled (when applicable).

**5.8 Data analysis:** Analysis will be performed using Stata 10 (StataCorp LP, College Station, TX).

- 1) The primary analyses will use intention-to-treat data. The intention-to-treat group will be defined as all randomized subjects. Infants who are fed pumped breastmilk will be considered as breastfeeding. Exclusive breastfeeding will be defined as breastfeeding without introduction of alternatives to breastmilk. A secondary analysis looking only at women who received at least one injection of DMPA will also be performed.
- 2) Survival analysis will be used for all time series data, including time to discontinuation of breastfeeding and time to introduction of alternatives to breastmilk. Data will be censored at the last date of contact. Breastfeeding will be the outcome variable. The log-rank test will be used for unadjusted comparison of the groups and presented graphically using a Kaplan-Meier curve. Cox proportional hazards model will be used to control for age, race, education, marital status, and prior breastfeeding experience while examining the association between timing of DMPA administration and discontinuation of breastfeeding.
- 3) Normally distributed continuous variables will be compared using Student's t-tests. The Mann-Whitney rank-sum test will be used to compare other continuous variables. Proportions will be compared using chi-square tests or Fisher's exact tests as appropriate.

### **5.9 Number of subjects and statistical power**

We previously found in a randomized study comparing postplacental and delayed LNG-IUD insertions that only 9% of subjects receiving a postplacental LNG-IUD were breastfeeding at 6 months compared to 41% of subjects receiving a delayed LNG-IUD.(4) We expect breastfeeding continuation rates will be higher in this study since we will be recruiting women who intend to breastfeed. A sample size of 70 per group achieves 80% power ( $\beta=0.20$ ) to detect a difference of 25% between the null hypothesis that the proportion of breastfeeding continuation at 6 months is 0.60 for both groups and the alternative hypothesis that the proportion in group 1 is 0.35 with a significance level of 0.05. With an estimated 10% discontinuation rate prior to randomization and 15% loss-to-follow-up, we plan to enroll 184 subjects

total. Sample size calculations were performed with the two-sided Fisher's Exact test using PASS 2005 (NCSS, Kaysville, UT).

Group 1 (on discharge)	Group 2 (4-6 weeks)	Sample size per group	Total sample size	Including 10% discontinuation/15% LTFU
0.15	0.4	56	112	147
0.25	0.5	64	128	168
<b>0.35</b>	<b>0.6</b>	<b>70</b>	<b>140</b>	<b>184</b>
0.45	0.7	69	138	182

**5.10 Project management:** The study will be coordinated by the Center for Family Planning Research, located in Magee-Womens Hospital at the University of Pittsburgh, which has performed a broad array of family planning research since 1994. The principal investigator and the research coordinator will be responsible for daily monitoring of subject safety. Enrollment, outcomes, and adverse events will be reviewed during biweekly meetings of the investigators and staff. The office has locked storage areas for maintaining subject files. All computers used for database management have firewalls and antivirus software that are updated regularly.

### **5.11 Anticipated difficulties**

One concern with any clinical trial is recruitment. In our prior experience with postplacental IUDs, we were able to recruit 163 subjects antenatally within one year. At our institution in 2010, approximately 10,000 deliveries were performed, 68% of women attempted breastfeeding and 1000 women received DMPA. Accordingly, we estimated about 680 women annually would be eligible for this study. At time of initiation of this study, we expected to enroll 25% of eligible women, which meant recruitment should take 13 months. However, due to slower than expected recruitment, a modification was approved on 8/16/13 to permit postpartum enrollment of participants. Since then, 62 participants have been enrolled over the past 13 months. However, recruitment has still been slower than expected, thus a modification to enroll women who would like to use DMPA as a short-term ("bridge") method of contraception before starting a more effective contraceptive such as an IUD, implant, or sterilization was created. This modification will still allow us to answer the specific aims of the study and is anticipated to improve recruitment.

We anticipate that some subjects will decide not to breastfeed between enrollment and delivery or may become ineligible due to exclusion criteria diagnosed after enrollment, thus we plan to enroll an additional 10% to account for pre-randomization exclusion. We also anticipate that it will be difficult to contact all subjects at each scheduled contact within the target dates. However, our experience with prior postpartum contraception studies is that postpartum women are motivated and willing to follow-up. In

addition, we will request permission to contact the subjects' physicians' and pediatricians' offices in order to obtain information about contraceptive continuation and breastfeeding to minimize loss-to-follow-up.

We also anticipate that many women may choose to discontinue DMPA for various reasons such as intolerance of irregular bleeding or may choose not to start DMPA at their 4-6 week visit. The planned modification to allow women to use DMPA as a "bridge" to more effective contraceptive methods (IUD, implant, sterilization) will allow women who do not start DMPA at their 4-6 week visit because of starting a more effective method of contraception at that time to be included in the analysis. We plan to analyze outcomes based on intention-to-treat (ITT) and also plan to perform a secondary analysis for women who received at least one dose of DMPA. Because this is a randomized trial, the ITT analysis will allow extrapolation of the data to more real life situations. The number of women who do not attend their postpartum visit or receive DMPA at their 4-6 week visit will be an important outcome since if DMPA has an effect on breastfeeding, women may need to weigh the advantages and disadvantages of immediate postpartum DMPA for contraception with potential effects on breastfeeding.

## **6. LINKS WITH OTHER PROJECTS** None

**7. EXPECTED OUTCOMES** We anticipate that these results will be highly relevant to postpartum women and their clinicians. The results will be presented at a national conference and published in peer-reviewed journals. The data from this study will be used to support a proposal to the National Institute of Child Health and Human Development (NICHD) to study additional intervals of postpartum DMPA administration over a longer follow-up period (e.g. 1 year) in order to assess contraceptive continuation, postpartum contraceptive switching, and infant outcomes including weight gain and growth.

## **BUDGET JUSTIFICATION**

### **Non-patient care costs**

Participant reimbursements include in-person visits (screening and enrollment, postpartum visit for randomization) and postpartum telephone contacts. In-person visits will be reimbursed at \$25 for the screening/enrollment visit and \$20 for the postpartum visit while in the hospital. Telephone contacts will be reimbursed at \$10 each until the final phone call, which will be reimbursed at \$15. We anticipate that 184 subjects will undergo a screening & enrollment visit and that 10% will discontinue prior to randomization. Thus, we expect that 165 subjects will undergo the postpartum visit prior to discharge and contacts at weeks 2, 4, 6, 8, and 12. We anticipate that 140 subjects will be contacted at weeks 16, 20, 24, and 28 due to an estimated 15% loss to follow-up. Subjects will follow up with their primary obstetrician or midwife for routine postpartum care and for contraception. Additional costs include paper supplies for charts for each subject (estimated \$10 per chart).

### **Clinical staff**

We anticipate that the bulk of the cost will be for personnel time to conduct the telephone interviews and to see subjects postpartum prior to hospital discharge. The budget includes 40% effort for a research assistant and 5% for a research coordinator over a period of 21 months (the length of the study from IRB submission to data analysis). The budget will also include 10% effort of the principal investigator over 24 months (the length of the study from IRB submission to dissemination of findings and development of grant proposals). The institutional benefits rate is 26.9% for physicians and 23.3% for non-physician staff. Indirect costs will be budgeted at 20%.

## TIMELINE

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## **BIOSKETCHES**

## **APPENDICES**

Edinburgh Postnatal Depression Scale

Infant Feeding Intentions Scale