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# Two-week postpartum intrauterine contraception insertion: a study of feasibility, patient acceptability and short-term outcomes☆,☆☆,★

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## Abstract

**Objective:** To determine the feasibility and acceptability of inserting the levonorgestrel intrauterine system, LNG 52 mg IUS (LNG IUS), at 2 weeks postpartum.

**Study design:** This prospective study of feasibility and patient acceptability recruited women interested in a postpartum LNG IUS and placed the LNG IUS under ultrasound guidance on days 14–20 postpartum. We determined feasibility by our ability to recruit and insert the LNG IUS in our predetermined sample size of 50 women. We measured our primary acceptability outcome at 6 months postpartum with the question: "Would you recommend Mirena placement at 2 weeks postpartum to a friend?" Other outcomes included expulsion and pain. The three study visits consisted of (1) insertion visit (14–20 days postpartum), (2) standard postpartum visit with a string check (6 weeks postpartum) and (3) research visit with sonography and assessment of the primary outcome (6 months postpartum).

**Results:** We enrolled 50 women over 8 months, all of whom received LNG IUS. Forty-three of the 50 (86%) provided follow-up data for the primary outcome. Of those, 93% (40/43) would recommend 2-week LNG IUS insertion to a friend, and 86% (37/43) continued using their LNG IUS at the conclusion of the 6-month visit. There were two partial expulsions; one was symptomatic. There were no uterine perforations.

**Conclusions:** LNG IUS inserted at 2 weeks postpartum is feasible and acceptable to patients. These results offer evidence to support intrauterine contraception insertion prior to the onset of ovulation and at a potentially more convenient time point in the postpartum period.

**Implications:** This study supports offering the LNG IUS beginning on the 14th postpartum day. The 4% expulsion rate is consistent with the rate of interval insertion and lower than immediate postplacental insertion. Additional research is needed to ensure a low risk of adverse events with other brands of intrauterine contraception.



*Keywords:* Intrauterine device; Postpartum contraception; Intrauterine device insertion; LARC; Levonorgestrel intrauterine system; LNG IUS

## 1. Introduction

Intrauterine contraception (IUC), the most common form of long-acting reversible contraception in the United States [1], has been shown to reduce rapid, repeat pregnancy [2]. Short interpregnancy intervals occur in one-third of all pregnancies in the United States [3]. These pregnancies, when unintended, cause women to choose between having an abortion or a pregnancy with an increased risk of preterm delivery and maternal-fetal complications [4]. Experts have recently advocated for a postpartum clinic visit earlier in the postpartum period, which could have the benefits of

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increased convenience and provide an opportunity to initiate effective contraception prior to the resumption of ovulation [5–7].

Initiating IUC earlier than 6 weeks [8] but later than postplacental [9–13] may provide women with more options for postpartum contraception. The ultimate goal of increased IUC use is a decrease in the unintended pregnancy rate. Research in immediate postplacental IUC insertion has demonstrated higher expulsion rates compared with interval insertion, with an immediate postplacental IUC insertion expulsion rate of 18% [7,9,14]. This high expulsion rate combined with logistical and billing challenges has limited widespread use in the United States [6,9–13]. However, these same data support the overall safety of immediate postpartum IUC insertion [9,10,12,13]. The option to place IUC in the clinic at 2 weeks postpartum has physiologic potential to have reduced expulsion compared to postplacental insertion [15]. Therefore, insertion at 2 weeks postpartum may increase IUC use and retention in this fertile population. However, it is not known if women would be interested in having an IUC inserted in the second postpartum week, or if those women would find the insertion acceptable. This study was conducted to determine the feasibility and acceptability of IUC initiation 2 weeks after a singleton birth.

## 2. Materials and methods

We conducted a prospective cohort study at North Carolina Women's Hospital in Chapel Hill, North Carolina, and obtained institutional review board approval from the University of North Carolina Office of Human Research Ethics. Prior to initiating the study, we registered the study at clinicaltrials.gov (NCT02121067), and the study is compliant with STrengthening the Reporting of OBservational studies in Epidemiology guidelines [16].

North Carolina Women's Hospital is a public, not-for-profit academic medical center that provides prenatal care for approximately 2500 patients annually and performs approximately 3500 deliveries annually. In 2013, the prenatal care population was composed of 20% African American, 13% Latina and 58% white women, with approximately one-third of patients covered by Medicaid or emergency Medicaid (36%). At North Carolina Women's Hospital, the postpartum visit usually occurs at 6 weeks postpartum. At the time of the study, the hospital did not routinely offer IUC for inpatient placement during the delivery hospitalization.

We screened women at the prenatal clinics at the North Carolina Women's Hospital clinics where patients are cared for by resident physicians, attending physicians and nurse-midwives. Study staff screened the medical records of women in the prenatal clinics at the hospital, as well as on the postpartum floor, to identify those who had documented interest in using the levonorgestrel (LNG) 52 mg intrauterine system (IUS) postpartum (Mirena®; Bayer Healthcare, Whippany, NJ, USA). Providers also referred women directly to the study. Study staff approached identified women to discuss the study and explained information related to eligibility requirements, study activities and follow-up needs. We created a tracking record of women who expressed interest in the study and compared the tracking record with the postpartum census on a daily basis. Study staff saw these women on the postpartum ward and scheduled an enrollment visit on days 14–20 postpartum. Enrollment visits were scheduled if women expressed sufficient interest in the study and desired to make an appointment. If a woman desired more time to consider the study, study staff contacted her by phone prior to day 14 postpartum. These women could then make the decision regarding the study over the phone, and when interested, study staff scheduled an enrollment visit.

At the enrollment visit, we rescreened women to ensure they met all eligibility requirements. These requirements included being age 18 to 45 years, speaking English or Spanish and desiring to use the LNG IUS as their contraception method. Further inclusion criteria included that the newborn must have been a singleton fetus delivered at ≥32 weeks' gestation. Exclusion criteria included that women must not have had a prior allergic reaction to any component of the LNG IUS, and women could not have a health condition that would make the LNG IUS a category 3 or 4 per the 2010 Center for Disease Control and Prevention's Medical Eligibility Criteria [17]. Finally, women were excluded if they experienced any of the following during or after delivery: a fourth-degree perineal laceration, uterine rupture, postpartum endometritis or retained tissue requiring a dilation and curettage. After completing this screening, we obtained written informed consent and enrolled the patient into the study.

We collected data at enrollment (14–20 days postpartum), 6 weeks postpartum and 6 months postpartum. Fellow and attending physicians within the Division of Family Planning placed the LNG IUS at the enrollment visit. Due to the experimental time frame for insertion of the LNG IUS, we performed insertions under abdominal ultrasound guidance. During visit 1, we collected the following data: demographics, reproductive history, ultrasound measurements of uterine size and physician assessment of ease of LNG IUS placement. We performed all LNG IUS placements using the manufacturers' inserter, after which we obtained ultrasound pictures confirming fundal placement. Immediately following LNG IUS placement, we used a visual analog scale (VAS) of 0–100 mm to measure the pain at bimanual exam and LNG IUS insertion. We did not administer any periprocedural pain medication or cervical anesthetic during insertion.

Study staff came to each woman's regularly scheduled 6-week postpartum visit with her obstetric care provider. Women completed a study questionnaire that covered changes to her health, LNG IUS satisfaction and potential symptoms such as uterine bleeding. Additionally, the provider, who was not a member of the study team,

performed a pelvic exam and string check. The provider confirmed the presence of the LNG IUS strings and managed any other problems or complications (such as partial expulsion or the need to cut the LNG IUS strings).

Women attended a final study visit at 6 months postpartum which included a speculum exam and transvaginal sonography to ensure the LNG IUS was in the proper uterine location. Women also completed a questionnaire to provide the primary outcome data: a dichotomous response to the following question: "Would you recommend Mirena placement at 2 weeks postpartum to a friend?" Upon completion of this visit, the women received their final installment of study compensation. Participants who were unable to attend the final study visit completed the questionnaire via phone.

We defined feasibility as the ability to enroll 50 women within 12 months, and the ability to insert at least 50% of attempted LNG IUSs. We also deemed this sample size of 50 women to be sufficient to measure acceptability, which is supported by other contraceptive research evaluating similar acceptability outcomes [18–21].

The data analysis plan was descriptive, including frequencies, chi-square and *t* tests where appropriate and nonparametric testing when data were not normally distributed. Bivariate testing was performed to evaluate the associations of mode of delivery, parity and previous IUC use with pain on insertion. Previous studies of perceived pain as measured on a VAS have determined that a difference of 15 mm is considered clinically significant [22–24]. We used STATA 13.0 (StataCorp LP, College Station, TX, USA) for all analyses. Study data were managed using the Web-based REDCap (Research Electronic Data Capture) electronic data system.

## 3. Results

We screened 242 women from September 2014 to April 2015 and scheduled 31% (74/242) of these women for a 2-week insertion visit (Fig. 1). Sixty-eight percent (50/74) of these women presented to the 2-week insertion visit. Forty-nine of the 50 insertion visits occurred between days 14 and 20 postpartum. One participant had her LNG IUS placed on day 13 due to an impending weather event. We were able to obtain primary outcome data at 6 months postpartum for 43 women (43/50; 86%).

The cohort is diverse (Table 1) and represents the population who receive care at the North Carolina Women's Hospital. The majority of enrolled women were not primarparous and their recent delivery was vaginal. Thirty percent (15/50) of the cohort had used IUC previously. The median time from delivery to insertion was 16 days [interquartile range (IQR) of 14–18].

For our primary acceptability outcome, 93% (40/43) of participants reached at 6 months postpartum would recommend 2-week LNG IUS insertion to a friend (Table 2). When assessed immediately following insertion, all but one participant (98%, or 49/50) recommended 2-week insertion to a friend. Most women (38/43, or 88.4%) were satisfied with their LNG IUS at 6 months. At the 6-month visit, 74% (32/43) of respondents preferred the 2-week time period to other insertion times in the postpartum period. Median VAS pain scores obtained immediately following insertion were low for both women with vaginal and cesarean deliveries at 5 (IQR: 0–26) and 29 (IQR: 6–49) respectively (Table 3). This 24 mm difference is both clinically and statistically significant (p=.03). Pain with LNG IUS insertion did not differ significantly between primiparous and multiparous women or women with and without previous IUC use. Eighty-one percent (29/36) of women who completed the 6-month visit in person had visible LNG IUS strings.

Two expulsion events occurred. Both were partial expulsions that were identified at a study visit, one of which was symptomatic. Physicians removed the original LNG IUSs and inserted a replacement LNG IUS in one subject. Three other participants requested their LNG IUSs to be removed prior to the 6-month study visit. One of these participants desired to conceive, and two others had pain and bleeding. Two additional women requested LNG IUS removal at the time of the 6-month study visit. No intervention-related adverse events occurred, and specifically there were no uterine perforations or infections. The 6-month continuation rate among those that provided 6-month follow-up data was 86% (37/43).

## 4. Discussion

Placing an LNG IUS at 2 weeks postpartum was feasible and acceptable in our population. Over 8 months, 68% (50/74) of those who scheduled an insertion visit presented for that appointment at 14–20 days postpartum. We were able to insert an LNG IUS in all 50 women without any immediate complications, and the vast majority (93%) of those who we reached at 6 months postpartum found the insertion acceptable.

Our study adds to the growing body of evidence supporting the initiation of highly effective contraception shortly after pregnancy and is the only study that includes in-clinic insertion starting at day 14 postpartum. We achieved an 86% follow-up rate at 6 months postpartum in a diverse patient population. Additionally, we demonstrated the feasibility of offering women LNG IUS insertion at an underinvestigated time point in the postpartum period, starting at day 14 postpartum [9]. Consistent with the only published in-clinic trial evaluating early (3 weeks) vs. routine (6 weeks) postpartum IUC insertion [8], women with early placement were more satisfied than women with routine placement [8]. Moreover, in their large trial (*n*=201), there were no differences between early or routine IUC insertion for important outcomes including safety, IUC continuation rates and pregnancy rates at 6 months [8].

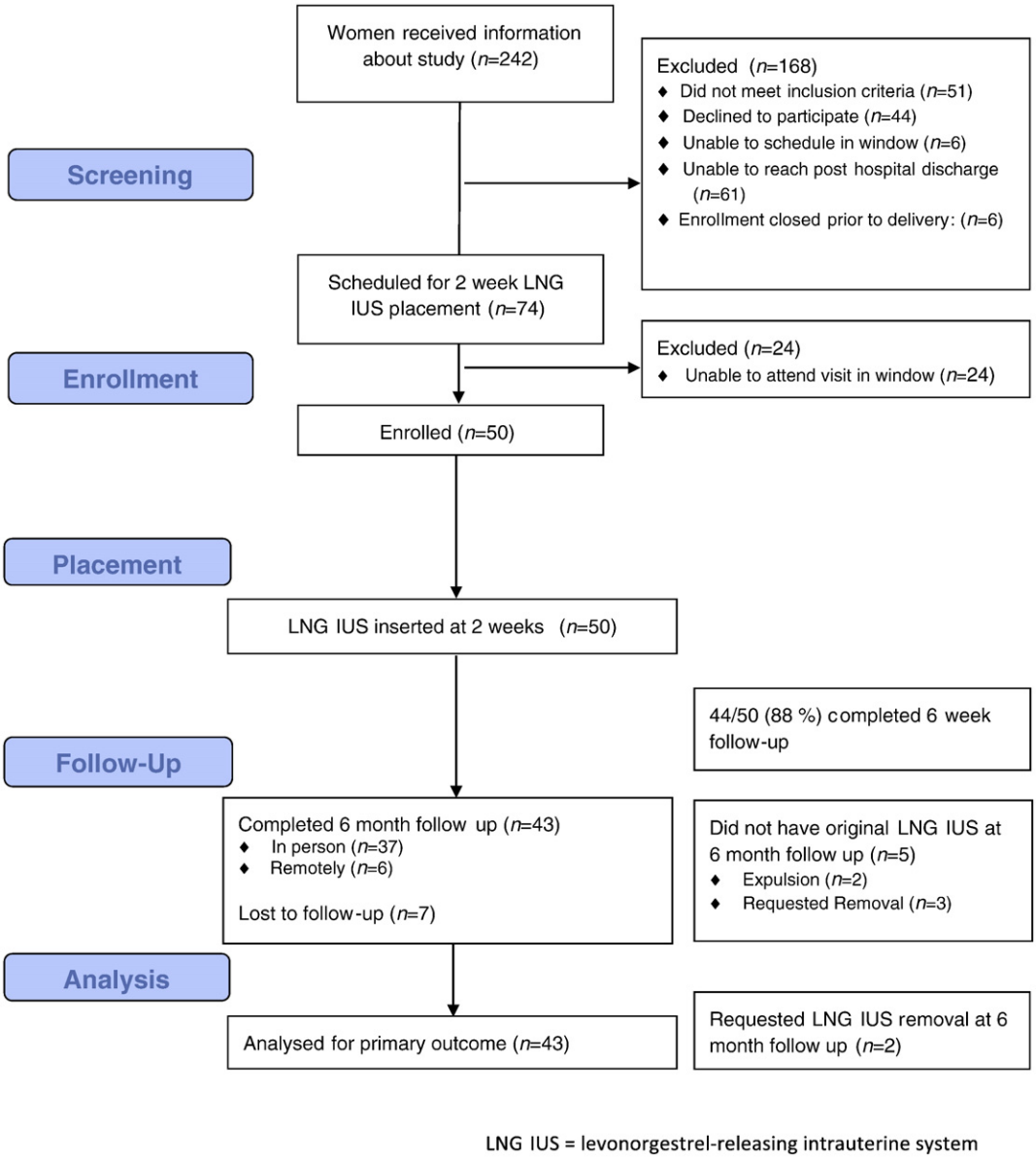


Fig. 1. Flow diagram of cohort participants.

We performed LNG IUS insertions under ultrasound guidance, and this may limit the generalizability of our results. We used ultrasound guidance because this was an understudied time period for insertion, and we wanted to reduce any theoretical risk of perforation. No perforations occurred, which is supported by the data from the Baldwin study in which 53 participants had IUCs placed on days 18–24 postpartum [8]. Taking the outcomes of these two studies together, we conclude that ultrasound guidance is not necessary in a clinical practice setting. An additional limitation in our study is that experienced family planning physicians performed all LNG IUS insertions. Although this could limit the generalizability, our conclusion is that 2-week placement is a reasonable option for postpartum contraception. All participants had successful 2-week postpartum LNG IUS insertions, and the vast majority of participants found the insertion acceptable.

Women with a cesarean delivery experienced more pain during LNG IUS insertion. From anecdotal information not captured by our survey instrument, some of this pain may have been due to the discomfort of the abdominal ultrasound probe pushing on the incision site. Therefore, the difference in pain among those with a recent cesarean delivery may diminish with elimination of the ultrasound guidance.

Offering IUC insertion around the 14th postpartum day can expand contraception options for women. This time point may be more convenient for some women compared to the traditional 6-week postpartum visit. Studies and experts

Table 1
Participant characteristics of enrolled women in the 2-week postpartum LNG IUS cohort

| Characteristic | *N*=50 |
|---|---|
| Age | 30 [24,36] |
| Parity | 2 [1,3] |
| Race | |
| White | 21 (42) |
| Black or African American | 15 (30) |
| Asian | 2 (4) |
| Hispanic | 12 (24) |
| Education | |
| <8 y | 2 (4) |
| Some high school | 5 (10) |
| High school or GED | 12 (24) |
| Some college | 18 (36) |
| College or bachelor's degree | 3 (6) |
| Graduate or professional school | 10 (20) |
| Employment status | |
| Employed full-time | 15 (30) |
| Employed part-time | 6 (12) |
| Unemployed | 23 (46) |
| Student[a] | 6 (12) |
| Household income | |
| $30,000 or less | 22 (44) |
| $30,001–$100,000 | 9 (18) |
| >$100,000 | 7 (14) |
| Don't know | 8 (16) |
| Declined | 4 (8) |
| Financial instability[b] | 4 (8) |
| Vaginal delivery | 37 (74) |
| Days from delivery to insertion | 16 [14,18] |
| Had sex prior to insertion | 1 (2) |
| Previous intrauterine device | 15 (30) |
| Size of uterus (cm), estimated by bimanual exam | 10 [9,12] |
| Sound length (cm) | 10.75 [9,12] |
| Periprocedure pain meds | |
| None | 39 (78) |
| NSAIDs | 10 (20) |
| NSAIDs and narcotics | 1 (2) |
| Physician reported difficulty LNG IUS insertion (1–10) | 3 [2,4] |
| LNG IUS placed by Family Planning fellow or attending | 50 (100) |

*n* (%) unless otherwise stated; median [1st,3rd quartiles].
NSAIDs, nonsteroidal anti-inflammatory.
[a] Any woman who identified as a student, even if partially employed, was considered a student.
[b] As determined by answering yes to the question: "In the last 30 days, have you been worried about having enough food for you or your family?"

suggest that the traditional 6-week postpartum visit is antiquated and an earlier visit may be more appropriate [5,8,25]. Additionally, IUC insertion at 2 weeks postpartum will offer yet another option for women to initiate effective contraception prior to the resumption of ovulation. Two weeks postpartum is also when women with medical conditions (diabetes, hypertension and depression) or who delivered via cesarean often return for obstetric visits. Furthermore, there may be an opportunity to combine an earlier IUC insertion visit with pediatric newborn check-ups, which occur at this time period as well. Based on the wealth of studies on IUC insertion throughout the postpartum period

Table 2
Reported acceptability at insertion and 6 months postpartum of enrolled participants in the 2-week postpartum LNG IUS study

| Reported acceptability variable | Insertion (*N*=50) | | 6 months postpartum (*n*=43) | |
|---|---|---|---|---|
| Recommend 2 weeks LNG IUS insertion to a friend | | | | |
| Yes | 49 | (98) | 40 | (93) |
| No | 1 | (2) | 3 | (7) |
| Satisfied with LNG IUS | | | | |
| Strongly agree/agree | – | | 38 | (88.4) |
| Neutral | – | | 2 | (4.7) |
| Disagree/strongly disagree | – | | 3 | (6.9) |
| Preference for time of postpartum LNG IUS insertion | | | | |
| 2 weeks | 47 | (94) | 32 | (74.4) |
| Earlier than 2 weeks | 1 | (2) | 1 | (2.3) |
| Later than 2 weeks | 2 | (4) | 5 | (11.6) |
| Missing | 0 | (0) | 5 | (11.6) |

*n* (%) unless otherwise stated.

[8–10,13,26], it appears that there is no single perfect time for all women. This study demonstrated a low prevalence of adverse events and adds support to the feasibility and acceptability of an earlier, clinic-based postpartum IUC insertion.

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Table 3
Reported VASs for pain at bimanual exam and LNG IUS insertion by delivery type, parity and previous IUC use among enrolled participants in the 2-week postpartum LNG IUS study

| Characteristic | VAS pain score[a] post-bimanual exam[b] | p Value[c] | VAS pain score[a] post-LNG IUS insertion[b] | p Value[c] |
|---|---|---|---|---|
| Delivery type | | | | |
| Vaginal delivery (*n*=37) | 7 [0,24] | .10 | 5 [0,26] | **.03** |
| Cesarean delivery (*n*=13) | 15 [0,29] | | 29 [6,49] | |
| Parity | | | | |
| Primiparous (*n*=20) | 10 [0, 16.5] | .30 | 2 [0,28] | .20 |
| Multiparous (*n*=30) | 14 [0,36] | | 17.5 [0,38] | |
| Previous IUC use | | | | |
| Yes (*n*=15) | 15 [0,27] | .56 | 11 [0,33] | .98 |
| No (*n*=35) | 11 [0,26] | | 8 [0,35] | |

Bold indicates a statistically significant difference in VAS scores.
[a] VAS pain score was on a scale of 0–100 mm, with 0 = no pain, and 100 = "worst imaginable pain."
[b] Median [1st,3rd quartiles].
[c] p Value calculated using Wilcoxon–Mann–Whitney test comparing different participant characteristics against reported pain.

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