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Original research article

A randomized trial of levonorgestrel intrauterine system insertion 6 to 48 h compared to 6 weeks after vaginal delivery; lessons learned☆,☆☆,★

Gretchen S. Stuart[a,*], Catherine R. Lesko[b], Alison M. Stuebe[a,c], Amy G. Bryant[a], Erika E. Levi[d], Antoinette I. Danvers[a]

[a]Department of Obstetrics and Gynecology, University of North Carolina School of Medicine, Chapel Hill, North Carolina 27599-7570
[b]Department of Epidemiology, Gillings School of Global Public Health, University of North Carolina, Chapel Hill, North Carolina, 27599
[c]Department of Maternal and Child Health, Gillings School of Global Public Health, University of North Carolina, Chapel Hill, North Carolina, 27599
[d]Department of Obstetrics & Gynecology and Women's Health, Albert Einstein School of Medicine, Bronx, New York

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Abstract

The objective of this randomized trial was to compare breastfeeding among women who received a levonorgestrel-releasing intrauterine system within 6–48 h (early) or 4–6 weeks (standard) after an uncomplicated vaginal birth. Analysis groups of 86 women in each arm were needed to demonstrate a 20% difference in any breastfeeding. Thirty-five women were randomized to the early (N=17) and standard (N=18) arms. The combination of unsuccessful placement (2/17; 12%), expulsions (7/17; 41%) and removals (3/17; 18%) reached 71% (12/17) in the early arm, so the study was stopped. In our small study cohort, levonorgestrel-releasing intrauterine system insertion between 6 and 48 h after vaginal birth was associated with a high rate of expulsion or removal soon after insertion.

Keywords: Postpartum; Contraception; Intrauterine device; Levonorgestrel; Family planning

1. Introduction

Provision of intrauterine contraception (IUC) immediately after childbirth can increase contraceptive uptake, especially for women who face challenges returning for a postpartum visit or obtaining the contraceptive method of their choice at their postpartum visit [1–3]. Immediate postpartum IUC placement can occur immediately after placenta delivery (postplacental), or up to 48 h postpartum [4–11]. An IUC can also be inserted right after cesarean birth, prior to closing the uterus [12–14]. Recent data from the United States indicate that immediate levonorgestrel-releasing intrauterine system (LNG-IUS) placement after vaginal birth is acceptable to women but is also associated with spontaneous expulsions occurring in 10%–38% of women by 6 months [6–8,15].

The advantages to women of waiting until 48 h after birth to place IUC may outweigh the risks of expulsion in certain settings. First, a longer time interval between birth and IUC insertion placement may be well suited for women who did not receive complete family planning counseling prior to delivery. Second, clinicians skilled at postpartum IUC placement are more likely to be available within a 48-h window of time; this is particularly relevant for practices in resource-poor settings and very busy clinical settings where a "morning after delivery" approach can be beneficial [9,16]. One barrier to wider use of the early postpartum LNG-IUS is conflicting data of the interactions between progestin-containing contraceptives and successful breastfeeding [1,17,18]. The primary objective of our study was to compare breastfeeding prevalence when the LNG-IUS is placed between 6 and 48 h (early) after vaginal delivery compared to placement at the standard postpartum visit

☆ Implications: Levonorgestrel-releasing intrauterine systems placed 6 to 48 h after vaginal delivery have a high chance of expulsion.

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★ Clinical Trial Registration: NCT 01555931 (Clinicaltrials.gov).

* Corresponding author at: 4004 Old Clinic, CB 7570. Tel.: +919 962 4880; fax: +919 843 6691.

E-mail address: gstuart@med.unc.edu (G.S. Stuart).

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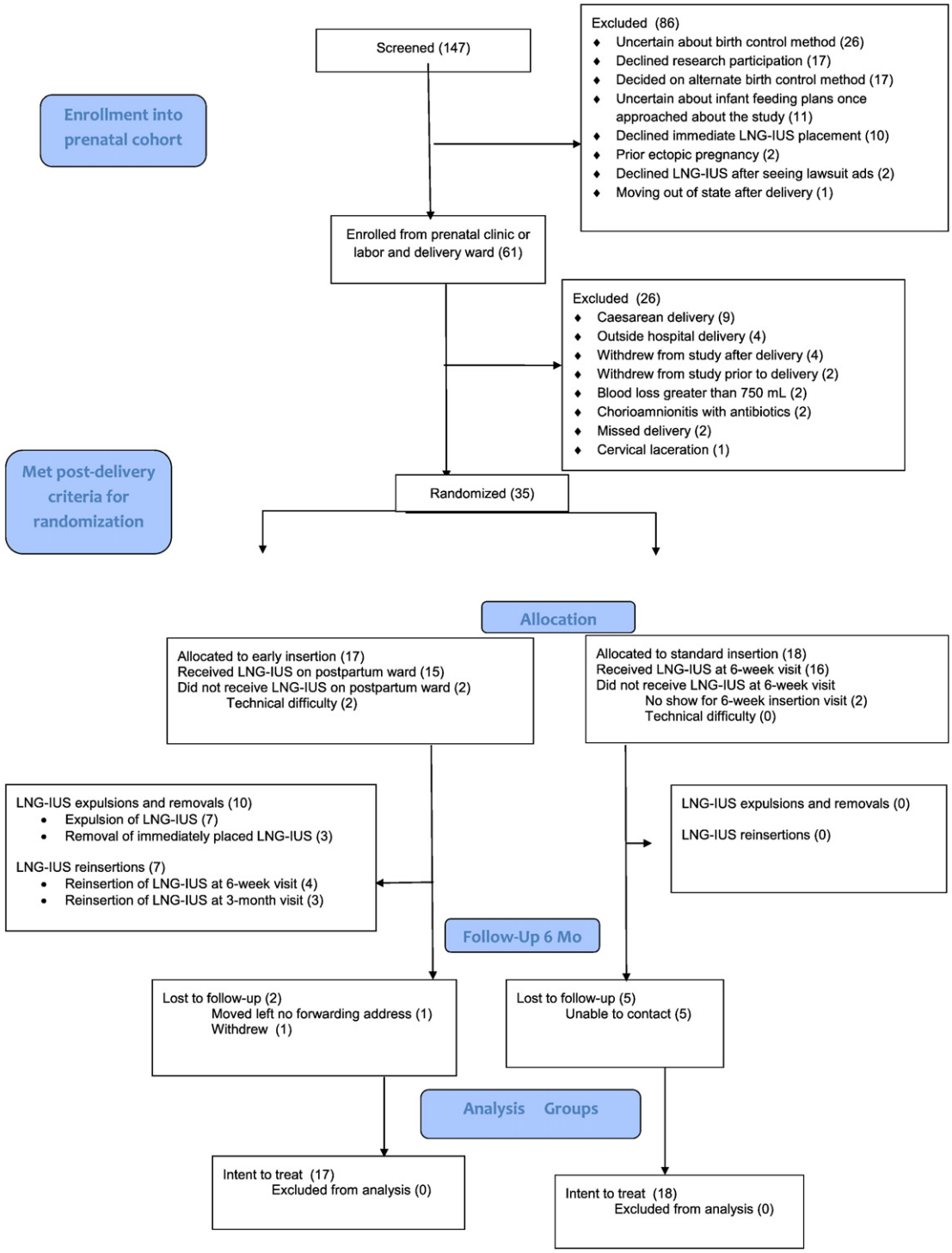

Fig. 1. Diagram of flow of study participants from screening through the final study visit.

(standard). However, early stoppage of this study due to an unacceptably high rate of spontaneous expulsion and removal in the early arm prevented answering the primary research objectives. Therefore, in this paper, we present lessons learned and data pertaining to the outcomes related to LNG-IUS placement only.

2. Materials and methods

This randomized clinical trial with 1:1 allocation was approved by the University of North Carolina Institutional Review Board and registered at Clinicaltrials.gov (NCT 01555931). Neither participants nor investigators were