

## GYNECOLOGY

# Placement of an intrauterine device within 48 hours after early medical abortion—a randomized controlled trial



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**BACKGROUND:** Intrauterine devices are safe, well-tolerated, and known to reduce the risk of unwanted pregnancies. At medical abortion, intrauterine devices are placed at a follow-up visit. Patients who miss this visit risk being left without contraception.

**OBJECTIVE:** This study aimed to investigate if placement of an intrauterine device within 48 hours of completed medical abortion at up to 63 days' gestation leads to higher user rates at 6 months after the abortion compared with placement at 2 to 4 weeks after abortion. Furthermore, we aimed to compare continued use of intrauterine devices, safety, and patient satisfaction between groups.

**STUDY DESIGN:** We performed an open-label, randomized, controlled, multicenter, superiority trial (phase 3). A total of 240 patients requesting medical abortion at up to 63 days' gestation and opting for an intrauterine device were allocated to placement within 48 hours of complete medical abortion (intervention group) or at 2 to 4 weeks after abortion (control group). We defined the abortion as complete after bleeding with clots and cessation of heavy bleeding following the use of misoprostol. Patients answered questionnaires at 3, 6, and 12 months. The primary outcome was use of intrauterine device at 6 months postabortion. Secondary outcomes included expulsion rate, pain at placement, adverse events and complications from the abortion, acceptability, and pregnancies and their outcomes. Differences in nonparametric continuous variables were analyzed with the Mann–Whitney U test and differences in dichotomous variables with the chi square or Fisher exact tests. A *P* value of  $<.05$  was considered statistically significant.

**RESULTS:** In the intervention group, 91 of 111 (82%) participants used an intrauterine device at 6 months after the abortion vs 87 of 112 (77.7%) in the control group, with a difference in proportion of 4.3% (95% confidence interval,  $-0.062$  to  $0.148$ ; *P* = .51). Attendance rate and rate of

successful intrauterine device placement were similar between the groups. Patients in the intervention group had lower pain scores at placement of the intrauterine device (mean pain score [visual analogue scale], 32.3; standard deviation, 29) compared with the control group (mean pain score [visual analogue scale], 43.4; standard deviation, 27.9; *P* = .002). Patients preferred their allocated time of placement significantly more often in the intervention group (83/111, 74.8%) than in the control group (70/114, 61.4%; *P* = .03). Use of ultrasound at intrauterine device placement (because of doubts concerning complete abortion) was more common in the intervention group (43/108, 39.8%) than in the control group (15/101, 14.9%; *P* < .001), and in one patient in the control group a retained gestational sac was found. Three patients in the intervention group and 2 in the control group had a vacuum aspiration. No difference was found in intrauterine device expulsion rates between the groups. Expulsion during the first 6 months after abortion was experienced by 9 of 97 (9.3%) patients in the intervention group and 4 of 89 (4.5%; *P* = .25) in the control group. There were no perforations or infections requiring antibiotic treatment.

**CONCLUSION:** Placement of an intrauterine device within 48 hours after medical abortion at  $\leq 63$  days' gestation does not lead to higher user rates at 6 months after the abortion compared with intrauterine device placement at 2 to 4 weeks after abortion. When compared with placement at a follow-up visit after 2 to 4 weeks, intrauterine device placement within 48 hours after early medical abortion seems safe, is preferred by patients, and is associated with lower pain scores.

**Key words:** contraception, copper intrauterine devices, family planning services, hormone-releasing intrauterine device, induced abortion, long-acting reversible contraception, medicated intrauterine devices, post-abortion intrauterine device insertion

## Introduction

Individuals having an abortion are often at risk for a new unplanned pregnancy with a subsequent need for abortion, and

have been shown to benefit from long-acting reversible contraception, such as intrauterine devices (IUDs).<sup>1</sup> Because fertility may return already 8 to 10 days after abortion, and resumption of sexual activity within few weeks of abortion is common, immediate initiation of contraception is important for patients who wish to avoid a subsequent pregnancy.<sup>2,3</sup> Sweden has the highest abortion rate in Western Europe (18/1000 women of fertile age). Half of the abortion cases are among individuals with at least 1 previous abortion.<sup>4</sup>

IUDs are safe, well-tolerated, and known to reduce the risk of unwanted pregnancies and subsequent need for abortions.<sup>1,5–7</sup> To increase access to immediate use of contraception after pregnancy, placement of an IUD at the time of cesarean delivery or after vaginal birth is routinely performed in many settings today. Infection and expulsion rates are low after planned cesarean delivery, whereas expulsion rates are considerably higher after vaginal birth.<sup>8–10</sup> IUD placement at the time of first-trimester surgical abortion is

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## AJOG at a Glance

**Why was this study conducted?**

We aimed to compare immediate placement of an intrauterine device (IUD) within 48 hours after medical abortion with placement at 2 to 4 weeks after abortion.

**Key findings**

Immediate IUD placement after medical abortion does not lead to higher user rates at 6 months after abortion compared with placement after 2 to 4 weeks.

Immediate IUD placement is safe, without increased rates of expulsion, perforation, or infection.

Immediate IUD placement results in lower pain scores and is preferred by patients.

**What does this add to what is known?**

This study provides evidence for clinical guidelines to include IUD placement within 48 hours after medical abortion and thereby improve patient satisfaction with maintained safety and improved access to IUDs.

well-studied and regarded as convenient, safe, and effective.<sup>11</sup> However, gradually since its introduction, medical abortion has become the primary method of choice in many settings (95% of abortions in Sweden), and many patients opt for IUD as postabortion contraception.<sup>4</sup> Moreover, the vast majority (85%) of abortions are early abortions at <63 days' gestation. In contrast to surgical abortion, IUDs are traditionally placed at a follow-up visit 2 to 4 weeks after a medical abortion. In Sweden, the current recommendation is to place IUDs after medical abortion within 1 week of misoprostol administration. However, adherence to this guideline is low.<sup>12</sup> Patients who miss this follow-up visit risk being left without contraception.<sup>13</sup>

Previous trials have examined the effectiveness and safety of IUD placement after medical abortion within 1 week of mifepristone administration or at a later time point.<sup>14,15</sup> However, these trials have been performed with an ultrasound examination before IUD placement as part of the protocol. These studies have shown similar expulsion rates with earlier and later times of placement and that postabortion endometrial thickness does not correlate to risk of IUD expulsion. Moreover, with earlier placement visits, these studies have shown that a greater proportion of

patients attend and that adverse events are few.<sup>14,15</sup>

In addition to these studies, Korjamo et al<sup>16</sup> performed a randomized controlled trial (RCT) with placement of a hormonal IUD within 3 days of misoprostol administration or at 2 to 4 weeks after medical abortion at up to 63 days' gestation. In this trial, rates of total IUD expulsion were comparable, but rates of partial expulsion were higher in the early group. The low number of participants (n=108) and a loss to follow-up rate of nearly 30% in the intervention group limit conclusions that could be drawn from this study.

Although guidelines include immediate placement of IUDs after medical abortion,<sup>17</sup> there have been, to the best of our knowledge, no previous studies on the placement of IUDs as early as within 48 hours after complete abortion without routine use of ultrasound after early medical abortion. The aim of this RCT was to compare the rate of IUD use at 6 months following medical abortion at up to 63 days' gestation between patients who had an IUD placed within 48 hours after complete abortion and those who had it placed 2 to 4 weeks after abortion. We hypothesized that placement of an IUD early after medical abortion would lead to placement rates of close to 100%. Furthermore, we

expected that early placement would increase the long-term use of IUDs with maintained safety and patient satisfaction.

**Materials and Methods**

The design was an open-label, randomized, controlled, multicenter, superiority trial (phase 3). We recruited patients aged  $\geq 18$  years requesting medical abortion with gestation of  $\leq 63$  days and opting for postabortion IUD at the gynecology clinics of Danderyd, Stockholm South General, Falun/Mora, Uppsala University, and Helsingborg hospitals in Sweden. Exclusion criteria were contraindications for medical abortion or IUD use, inability to give informed consent, and abortion-related complications (septic abortion, bleeding >1000 mL, uterine atony, and placental retention). We provided written and oral information about the study for patients with an appointment for medical abortion at the involved clinics who had chosen to have an IUD for postabortion contraception. All patients had the opportunity to ask questions and all study procedure followed the Declaration of Helsinki recommendations for physicians in biomedical research involving human subjects. After signing informed consent, we randomized patients who took mifepristone to placement of an IUD within 48 hours after complete abortion (intervention group) or to IUD placement at a scheduled follow-up visit 2 to 4 weeks after abortion according to routine care (control group). The abortion was defined as complete after patients reported bleeding with clots and cessation of heavy bleeding following the use of misoprostol and the providers found no reason to suspect an incomplete abortion on the basis of patient history. To confirm complete abortion, all patients took a low-sensitivity urine pregnancy test at 2 to 4 weeks after the abortion, either self-administered at home, or by clinic staff at a follow-up visit. The numbers of included patients were not expected to be equal at each site, which was considered in the statistical analysis. The randomization ratio between the intervention and control group was 1:1

in permuted blocks of 4 to 8. The study was approved by the Regional Ethics Committee of Stockholm (permit number 2016/1685-31/1) with an amendment for new study centers (permit number 2021-02625). The study was also approved by the European Medicines Agency (EudraCT number 2018-000287-29).

The medical termination of pregnancy was carried out according to the World Health Organization guidelines.<sup>18</sup> We performed a chlamydia polymerase chain reaction test, unless the patient actively abstained, and screening for bacterial vaginosis using Amsel's criteria. Patients with bacterial vaginosis received treatment started before or at the same time as the abortion. No routine antibiotics were given. Ultrasound verification of complete abortion was not mandatory according to protocol, except in the case of doubt concerning complete abortion. Included patients who had home administration of misoprostol and were allocated to the intervention group were scheduled for IUD placement within 48 hours of misoprostol administration. Patients treated in the clinic could have their IUD placed immediately after assumed complete abortion or return within 48 hours for placement. Patients in the control group were scheduled for an appointment for placement after 2 to 4 weeks. The study drugs approved for this study were: Mirena (levonorgestrel-releasing intrauterine system [LNG-IUS], 52 mg), Kyleena (LNG-IUS, 19.5 mg), Jaydess (LNG-IUS, 13.5 mg, marketed as Skyla in some countries), and NovaT 380 (Cu-IUD), manufactured by Bayer GmbH, Leverkusen, Germany. We placed all products according to the instructions by the manufacturer and provided all IUDs at no cost according to regulations by the Medical Products Agency. This is a deviation from clinical practice. In Sweden, women aged <26 years normally pay a sum corresponding to approximately \$10/€10 for the device. Women aged >25 years pay approximately \$95 for the hormonal IUDs used in this study. The placement visit is always provided for free within the healthcare system in Sweden if the IUD is placed by a nurse-midwife. The

copper IUD is provided for free in most settings. All IUDs were placed by staff at the same clinic. If a patient missed the placement visit, 3 attempts were made to reach the patient by telephone to reschedule.

Included patients were asked to participate in the study for 12 months. Follow-up was at 3, 6, and 12 months, either by a phone call and/or an e-mail with a link to a structured questionnaire with multiple questions related to the primary and secondary outcomes of the study. There was no mandatory follow-up visit after the IUD placement visit.

The primary outcome of the study was IUD use at 6 months postabortion, evaluated as the proportion of patients using IUD vs not using IUD. The secondary outcomes were rates of IUD placement at allocated time, reasons for nonplacement of IUD, expulsion rate, pain at placement, adverse events and complications from the abortion, acceptability, and pregnancies and abortions evaluated at the 3-, 6-, and 12-month follow-up.

We measured pain scores at IUD placement using a visual analogue scale (VAS) ranging from 0 to 100, where 0 is equal to no pain and 100 to the worst imaginable pain. We asked patients to indicate the pain before IUD placement, at placement of tenaculum, at sounding, at placement of the IUD, and before they left the clinic.

The rate of expulsion reported by patients was limited to complete expulsion because no clinical examination was undertaken to detect partial expulsion as part of scheduled follow-up. Partial expulsion could hence only be diagnosed at a clinically motivated visit or if patients felt the IUD.

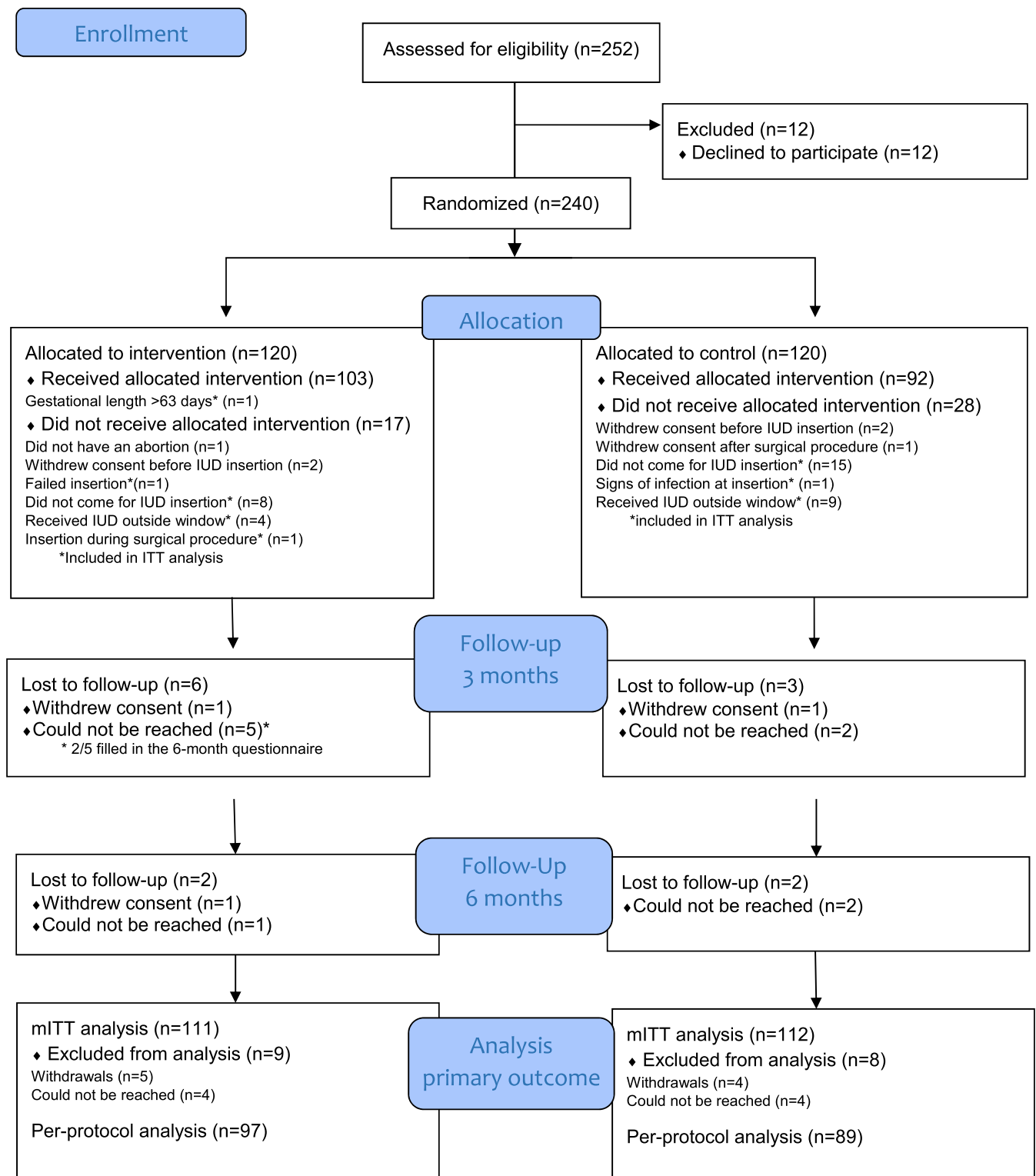
We hypothesized that the use of IUD 6 months after abortion would be at least 20% higher in the intervention group. The sample size was calculated on the basis of the hypothesis of 80% IUD use in the intervention group and 60% use in the control group at 6 months after abortion. Three percent to 5% were estimated to need a vacuum aspiration because of incomplete abortion and/or prolonged bleeding, and approximately 15% loss to follow-up was expected,

which is commonly observed in abortion studies. With a power of 90% and an alpha of 0.05, we needed to randomize 240 patients. An interim analysis was performed when 50% of patients had been recruited, with the predefined decision to stop inclusion in case of expulsion rates exceeding 20% or acceptability rates <50% at the 3-month follow-up in any group.

We performed statistical analyses using IBM SPSS Statistics for Windows, version 26 (IBM Corp, Armonk, NY). The main analysis for the primary outcome was a modified intention-to-treat (mITT) analysis including all randomized patients with medical abortion and follow-up recorded at 6 months. Hence, also patients with no IUD placement and patients experiencing expulsion were included in the mITT population. The analyses included the full dataset, and all results were based on observed outcomes without imputation of missing data. Nonparametric continuous variables are presented as medians with minimum and maximum values; differences between groups were analyzed by the Fisher exact test. Dichotomous variables are presented as proportions with differences between groups analyzed by the chi square or Fisher exact test, as appropriate. All differences between groups were considered as statistically significant if they had a *P* value <.05.

## Results

From January 2019 to February 2021, a total of 240 patients having early medical abortion at up to 63 days' gestation and opting for IUD postabortion were included in the trial. The flow of patients is described in Figure 1. A total of 120 patients were randomized to IUD placement within 48 hours after assumed expulsion of the pregnancy, and 103 (85.8%) of these received the allocated intervention. We randomized 120 patients to the control group with IUD placement after 2 to 4 weeks. Of these, 92 (76.7%) received the allocated intervention. Three patients were excluded in the intervention group because of withdrawal of consent (*n*=2) or not having an abortion (*n*=1). In the

**FIGURE 1**  
**CONSORT 2010 flow diagram**

CONSORT, Consolidated Standards of Reporting Trials; ITT, intention-to-treat; IUD, intrauterine device; mITT, modified intention-to-treat.

Hogmark. Immediate vs delayed placement of intrauterine devices after early medical abortion. *Am J Obstet Gynecol* 2023.

control group, 3 patients withdrew consent. The groups were comparable regarding baseline characteristics and the IUDs chosen (Table 1).

This report includes analysis of primary outcome and secondary outcomes at 6 months in an mITT analysis. For the primary outcome and for IUD expulsion rates, we also present per-protocol analyses. Patients in both groups who did not come for IUD placement, who had the IUD placed outside the allocated time window or during surgery, or for whom IUD placement failed were included in the mITT analysis but removed from the per-protocol population. One patient in the intervention group had 68 days' gestation and was included in the mITT analysis. In the intervention group, 91 of 111 (82%) (Table 2) used an IUD at 6 months after the abortion vs 87 of 112 (77.7%) in the control group, with a difference in proportion of 4.3% (95% confidence interval,  $-0.062$  to  $0.148$ ;  $P=.51$ ). A sensitivity analysis with imputation of the results with these proportions did not change results significantly.

Attendance rate and rate of successful IUD placement were similar between groups. In the intervention group, 108 of 117 (92.3%) patients attended the IUD placement visit. IUDs in the intervention group were placed at a median of 42 hours (interquartile range, 21–46 hours, minimum 0 and maximum 144 hours) after completed abortion, and all placements were successful except one. The failure was because of severe pain and inability to pass the IUD through the internal cervical os. The patient declined another try with anesthetics, and at 6 months postabortion she used condoms for contraception. In the control group, 103 of 118 (87.3%) patients attended the IUD placement visit. There were 3 failed placements. Two were owing to severe pain, and the third one was because of signs of infection. Of the 2 patients with severe pain at placement, one had an IUD placed under general anesthesia later on, but then withdrew consent to continue participation. The other patient withdrew consent when contacted at the 3-month follow-up. The patient with signs of infection had an IUD

**TABLE 1**  
**Baseline characteristics**

Characteristics	Intervention (n=120)	Control (n=120)
<b>Demographic characteristics</b>		
<b>Age</b>		
Median	31	30
IQR	26–35	26–35.75
Min-max	18–48	18–48
Missing	1	
<b>Number of school years, n (%)</b>		
≤9	3 (2.5)	6 (5)
10–12	60 (50.4)	58 (48.3)
>12	56 (47.1)	56 (46.7)
Missing	1	
<b>Other baseline characteristics</b>		
<b>Gestational age at mifepristone intake</b>		
Median	43	42
IQR	40–51.25	38–49.75
Min-max	28–68	28–63
Missing	2	
Parous women, n (%)	88 (73.3)	84 (70)
Previous abortion, n (%)	72 (60.5)	72 (60)
Missing	1	
Misoprostol taken at home, n (%)	104 (87.4)	101 (84.2)
Missing	1	
<b>Type of IUD placed, n (%)</b>		
Mirena	59 (54.6)	45 (44.1)
Kyleena	39 (36.1)	49 (48)
Jaydess	3 (2.8)	1 (1.0)
Copper IUD Nova T	7 (6.5)	7 (6.9)
IUD not placed	12	18

Baseline characteristics of patients having medical abortion at up to 63 days' gestation and opting for IUD as postabortion contraception (N=240).

IQR, interquartile range; IUD, intrauterine device.

Hogmark. Immediate vs delayed placement of intrauterine devices after early medical abortion. *Am J Obstet Gynecol* 2023.

placed later on, but became pregnant with an ectopic pregnancy, as described below.

The per-protocol analysis included all patients with medical abortion at ≤63 days' gestation and without surgical intervention who had an IUD placed within the allocated time window and who filled out the 6-month follow-up questionnaire. The per-protocol population

consisted of 97 patients in the intervention group and 89 in the control group. The use of IUD at 6 months was 84 of 97 (86.6%) (Table 2) in the intervention group and 79 of 89 (88.8%) in the control group ( $P=.82$ ).

Use of ultrasound at IUD placement was more common in the intervention group than in the control group ( $P<.001$ ). In the intervention group,

**TABLE 2**  
**Proportion of patients using an intrauterine device at 6 months**

IUD users	Intention-to-treat			Per-protocol		
	Intervention n=111	Control n=112	Pvalue	Intervention n=97	Control n=89	Pvalue
At 6 mo, n (%)	91 (82%)	87 (77.7%)	.51	84 (86.6%)	79 (88.8%)	.82

Intervention=placement of an intrauterine device within 48 hours after early medical abortion; control=placement of an intrauterine device at 2 to 4 weeks after early medical abortion. Proportions of patients using an intrauterine device at 6 months following early medical abortion (N=240). P value calculated with Fisher exact test.

IUD, intrauterine device.

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ultrasound was used in 43 of 108 (39.8%) patients. There were no patients with retained products of conception. In the control group, ultrasound was used in 15 of 101 (14.9%) patients, and in one patient a retained gestational sac was found. This patient had the IUD placed at the time of vacuum aspiration.

Pain scores were normally distributed. Patients in the intervention group had significantly lower pain scores at placement of the IUD (mean pain score VAS, 32.3; standard deviation [SD], 29) compared with the control group (mean pain score VAS, 43.4; SD, 27.9;  $P=.002$ ). A description of pain scores at different points of measurement is shown in [Figure 2](#).

Healthcare providers rated the ease of IUD placement as very easy/easy/neither easy nor difficult in 106 of 108 (98.1%) of the patients in the intervention group and as difficult/very difficult in 2 of 108 patients (1.9%). Corresponding numbers in the control group were 93 of 101 (92.1%) and 8 of 101 (7.9%), respectively ( $P=.05$ ). Patients preferred their allocated time of IUD placement significantly more often in the intervention group (83/111, 74.8%) than in the control group (70/114, 61.4%;  $P=.03$ ).

A total of 3 patients in the intervention group had a vacuum aspiration after the medical abortion because of retained products of conception. In the control group, 2 patients had vacuum aspiration.

There were no perforations or infections requiring antibiotic treatment.

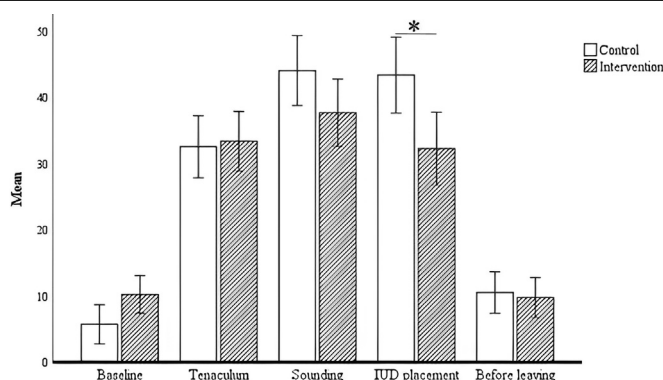
No difference was found in IUD expulsion rate between the groups according to the mITT analysis ([Table 3](#)). IUD expulsion during the first 6 months after abortion was experienced by 10 of 111 (9.0%) patients in the intervention group (7 parous and 3 nulliparous) and 4 of 112 (3.6%;  $P=.11$ ) patients in the control group (2 parous and 2 nulliparous). At 6 months after the abortion, 4 of the 14 patients who had experienced IUD expulsion were using an IUD. All expelled IUDs were hormonal IUDs (10 Mirena and 4 Kyleena). In the per-protocol analysis of expulsion rates, the difference was also not significant ( $P=.25$ ) ([Table 3](#)).

Within 3 months after the abortion, 1 patient in each group became pregnant. The patient in the intervention group had not returned for IUD placement and had a subsequent abortion. The patient in the control group had an ectopic pregnancy with a Kyleena in situ, which was removed at the time of surgery. During the time period of 3 to 6 months after the abortion, 4 patients in the intervention group and 3 patients in the control group became pregnant. Among the patients in the intervention group, 1 had not come for IUD placement and decided to keep the pregnancy. One had an expulsion of a Kyleena and had an abortion. Two patients had had their Mirena extracted because of side effects. At the 6-month follow-up, none of these 2 patients had decided how to proceed with the pregnancy. In the control group, the patient with an ectopic pregnancy at 3 months became pregnant again and decided to keep that pregnancy. One patient did not come for placement and had a miscarriage. One patient had a copper IUD extracted because of side effects, became pregnant again, and had a miscarriage.

## Comment

### Principal findings

Placement of an IUD within 48 hours after complete abortion with  $\leq 63$  days' gestation does not lead to higher user rates 6 months after the abortion compared with IUD placement at 2 to 4

**FIGURE 2**  
**Mean pain score during placement of intrauterine devices**

Error bars represent  $\pm 2$  standard errors. Asterisk indicates significant difference.

IUD, intrauterine device.

Hogmark. Immediate vs delayed placement of intrauterine devices after early medical abortion. *Am J Obstet Gynecol* 2023.

**TABLE 3**  
**Expulsions of intrauterine devices by time postabortion**

Time postabortion	Intervention			Control			P value, overall expulsions
	Complete n (%)	Partial n (%)	Overall n (%)	Complete n (%)	Partial n (%)	Overall n (%)	
<b>Within 3 mo</b>							
mITT	4/112 (3.6)	4/112 (3.6)	8/112 (7.1)	2/114 (1.8)	1/114 (0.9)	3/114 (2.6)	.13
Per-protocol	4/97 (4.1)	3/97 (3.1)	7/97 (7.2)	2/89 (2.2)	1/89 (1.1)	3/89 (3.4)	.33
<b>Between 3–6 mo</b>							
mITT	2/111 (1.8)	0	2/111 (1.8)	1/112 (0.9)	0	1/112 (0.9)	.62
Per-protocol	2/97 (2.1)	0	2/97 (2.1)	1/89 (1.1)	0	1/89 (1.1)	1.00
<b>Within 6 mo</b>							
mITT	6/111 (5.4)	4/111 (3.6)	10/111 (9.0)	3/112 (2.7)	1/112 (0.9)	4/112 (3.6)	.11
Per-protocol	6/97 (6.2)	3/97 (3.1)	9/97 (9.3)	3/89 (3.4)	1/89 (1.1)	4/89 (4.5)	.25

Expulsions of intrauterine devices within 6 months following medical abortion. P values calculated with Fisher exact test.

mITT, modified intention-to-treat.

Hogmark. Immediate vs delayed placement of intrauterine devices after early medical abortion. *Am J Obstet Gynecol* 2023.

weeks after abortion. When compared with placement at a follow-up visit after 2 to 4 weeks, IUD placement within 48 hours after early medical abortion seems safe, is preferred by patients, and is associated with lower pain scores.

### Results in the context of what is known

The relatively high attendance for placement in our study may be explained by booked appointments for follow-up at the abortion clinic, and additionally, provision of IUDs for free. Korjamo et al and Sääv et al<sup>15</sup> both performed their studies in high-resource settings similar to ours, with the Sääv study performed in Sweden and the Korjamo study performed in Finland. In the Korjamo study, women were randomized to “fast-track insertion” within 3 days of misoprostol administration or placement at a visit 2 to 4 weeks after the abortion. In the Sääv study, women were randomized to IUD placement 5 to 9 days or 3 to 4 weeks after mifepristone administration. Both of these prospective studies had attendance rates >85% with follow-up at the abortion clinic.<sup>15,16</sup> In contrast, the Pohjoranta et al study,<sup>13</sup> also performed in Finland, retrospectively found

that 57% of patients attended follow-up at a primary healthcare center. These results support the positive impact of scheduled follow-ups, preferably at the abortion clinic.

Sääv et al<sup>15</sup> reported continued use of IUDs in 68% of participants in the intervention group and 72% in the delayed group. In 2011, Shimoni et al<sup>14</sup> studied IUD use in patients in New York, the United States, randomized to placement of a copper IUD within 1 week of mifepristone administration compared with 4 to 6 weeks after medical abortion. They reported a nonstatistical difference, with 69% use after 6 months in the intervention group and 60% in the control group. Korjamo et al<sup>16,19</sup> did not report IUD use at 6 months but at 1 year, at which continued use in patients with medical abortion at <64 days' gestation was only reported as “best” or “worst case” scenario. In the “best case” scenario, 80% in the immediate placement group and 71.7% in the delayed group used an IUD at 1 year,<sup>19</sup> as opposed to 82% in the intervention group and 77.7% in the control group at 6 months postabortion in our study.

Expulsion rate of IUDs in the control group in our study was comparable to

those of previous studies with placement of IUDs within 2 to 4 weeks after abortion.<sup>14,15,20</sup> In contrast, in the intervention group of our study, the 9.3% expulsion rate at 6 months postabortion was lower than the 12.5% expulsion rate at 3 months found by Korjamo et al.<sup>16</sup> However, most expulsions in the Korjamo study were asymptomatic partial expulsions, mainly diagnosed by vaginal ultrasound at a scheduled follow-up visit. We found similar expulsion rates in the early placement group in Sääv et al.<sup>15</sup> However, in that study the time of expulsion in relation to placement was not reported, nor did they differentiate between partial and total expulsion. Studies have not been able to show that ultrasound before IUD placement can predict risk of expulsion.<sup>21</sup> We actively chose not to include an ultrasound examination as part of our follow-up protocol to increase generalizability.<sup>18</sup> In our study, ultrasound examinations did not show any retained products of conception. Thus, our results are reassuring concerning the safety of early placement of IUDs after medical abortion without previous ultrasound examination. All patients had a low-sensitivity pregnancy test for

confirmation of abortion completion according to guidelines.

One hypothesis that has not been explored previously was that immediate IUD placement could be less painful than delayed placement because of dilation of the cervix after the abortion. We measured pain scores immediately on a VAS, and results clearly showed that patients in the intervention group had significantly lower pain scores during IUD placement compared with patients in the control group.

### Clinical implications

We have shown that placement of any IUD within 48 hours can be used in clinical settings with maintained effectiveness and safety. Expulsion rates were low and could have been because of minimal cervical dilation in early medical abortion. Early placement is preferred by patients and results in lower pain scores than placement after 2 to 4 weeks postabortion. We hypothesize that the lower pain scores are related to the naturally dilated cervix postabortion.

We observed high attendance rates for placement when IUDs are provided for free, and patients are given an appointment for placement at the abortion clinic. The fact that patients did not have to physically collect an IUD at the pharmacy, pay for the IUD, and book an appointment may have increased attendance for placement. Our results did not raise any concerns about the implementation of these practices into guidelines and clinical practice.

### Research implications

This study reports the primary outcome and secondary outcomes of our trial at 6-month follow-up. The study is part of a larger study in which placement of IUD within 48 hours after medical abortion is studied up to 22 weeks of pregnancy. The impact of gestational length and type of IUD on effectiveness, pain at placement, and risk of expulsion remains unknown. In addition, long-term continued use of IUDs after medical abortion remains to be explored.

### Strengths and limitations

The strength of this study was the robust RCT design. It was not deemed feasible to blind participants. The study size was larger compared with previous studies and powered to detect the stipulated difference, but we did not reach statistical significance in the primary outcome. Less common safety outcomes such as perforations and serious infections could not be assessed in a study of our size. We had a very low loss to follow-up rate for a study on abortion. It may be that patients who choose IUD for postabortion contraception constitute a subgroup among patients who have abortion. In addition, participation in a study differs from clinical practice and may attract a certain subset of patients. Two factors in our study design differ from clinical practice. One is that patients were provided with the device for free. This was a requirement of the Medical Products Agency. In addition, patients were given an appointment and did not have to contact a provider to arrange IUD placement. This also may have increased the proportion of patients who came for placement. Following guidelines for placement and not having ultrasound as a part of the protocol increases generalizability of results to settings where ultrasound is not accessible.

### Conclusions

Placement of an IUD within 48 hours after medical abortion with  $\leq 63$  days' gestation is safe and can be performed without ultrasound examination. It does not lead to higher user rates 6 months after the abortion, but is preferred by patients and associated with lower pain scores when compared with IUD placement at 2 to 4 weeks after abortion. ■

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### References

1. Heikinheimo O, Gissler M, Suhonen S. Age, parity, history of abortion and contraceptive choices affect the risk of repeat abortion. *Contraception* 2008;78:149–54.
2. Schreiber CA, Sober S, Ratcliffe S, Creinin MD. Ovulation resumption after medical abortion with mifepristone and misoprostol. *Contraception* 2011;84:230–3.
3. Boesen HC, Rørbye C, Nørgaard M, Nilas L. Sexual behavior during the first eight weeks after legal termination of pregnancy. *Acta Obstet Gynecol Scand* 2004;83:1189–92.
4. The National Board of Health and Welfare. Statistik om aborter. Socialstyrelsens. 2021. Available at: <https://www.socialstyrelsen.se/statistik-och-data/statistik/statistikamnen/aborter/>. Accessed March 20, 2022.
5. Rose SB, Lawton BA. Impact of long-acting reversible contraception on return for repeat abortion. *Am J Obstet Gynecol* 2012;206:37.e1–6.
6. Winner B, Peipert JF, Zhao Q, et al. Effectiveness of long-acting reversible contraception. *N Engl J Med* 2012;366:1998–2007.
7. Kilander H, Alehagen S, Svedlund L, Westlund K, Thor J, Brynhildsen J. Likelihood of repeat abortion in a Swedish cohort according to the choice of post-abortion contraception: a longitudinal study. *Acta obstet gynecol Scand* 2016;95:565–71.
8. Lopez LM, Bernholm A, Hubacher D, Stuart G, Van Vliet HA. Immediate postpartum insertion of intrauterine device for contraception. *Cochrane Database Syst Rev* 2015:CD003036.
9. Makins A, Taghinejadi N, Sethi M, et al. FIGO postpartum intrauterine device initiative: complication rates across six countries. *Int J Gynaecol Obstet* 2018;143:20–7.
10. Kapp N, Curtis KM. Intrauterine device insertion during the postpartum period: a systematic review. *Contraception* 2009;80:327–36.
11. Okusanya BO, Oduwole O, Effa EE. Immediate postabortal insertion of intrauterine devices. *Cochrane Database Syst Rev* 2014:CD001777.
12. Egardt A, Algovik M, Kopp Kallner H. Adherence to Swedish national recommendations for long acting reversible contraceptive provision at the time of medical abortion. *Contraception* 2021;103:261–4.
13. Pohjoranta E, Mentula M, Suhonen SP, Heikinheimo O. Predicting poor compliance with follow-up and intrauterine contraception services after medical termination of pregnancy. *BMJ Sex Reprod Health* 2018 [Epub ahead of print].
14. Shimoni N, Davis A, Ramos ME, Rosario L, Westhoff C. Timing of copper intrauterine device insertion after medical abortion: a randomized controlled trial. *Obstet Gynecol* 2011;118:623–8.
15. Sääv I, Stephansson O, Gemzell-Danielsson K. Early versus delayed insertion of intrauterine contraception after medical



abortion - a randomized controlled trial. *PLoS One* 2012;7:e48948.

16. Korjamo R, Mentula M, Heikinheimo O. Fast-track vs. delayed insertion of the levonorgestrel-releasing intrauterine system after early medical abortion - a randomized trial. *Contraception* 2017;96:344–51.

17. Abortion care guideline. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

18. World Health Organization. Medical management of abortion, vol. 2021; 2018.

19. Korjamo R, Mentula M, Heikinheimo O. Immediate versus delayed initiation of the levonorgestrel-releasing intrauterine system following medical termination of pregnancy - 1 year continuation rates: a randomised controlled trial. *BJOG* 2017;124:1957–64.

20. Betstadt SJ, Turok DK, Kapp N, Feng KT, Borgatta L. Intrauterine device insertion after medical abortion. *Contraception* 2011;83:517–21.

21. Shimoni N, Davis A, Westhoff C. Can ultrasound predict IUD expulsion after medical abortion? *Contraception* 2014;89:434–9.

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- v) Data will be made available upon request from the corresponding author

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