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The clinical trial identification number and the URL of the registration site

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ii) Date of initial participant enrollment January 16, 2019

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iv) URL of the registration site ClinicalTrials.gov

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

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1. **Condensation**

Intrauterine device placement within 48 hours after early medical abortion does not lead to higher user rates, but is safe, and preferred by patients compared with delayed placement.

2. **Short Title**

Immediate vs delayed placement of intrauterine devices after early medical abortion

3. **AJOG at a Glance:**

   A. 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 two to four weeks after abortion.

   B. What are the key findings?

   - Immediate IUD placement after medical abortion does not lead to higher user rates at six months after abortion compared with placement after two to four 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.

   C. What does this study add to what is already 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.
Abstract

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

To study if placement of an intrauterine device within 48 hours of completed medical abortion up to 63 days’ gestation leads to higher user rates at six months after the abortion compared with placement at two to four weeks after abortion. Furthermore, 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 up to 63 days’ gestation and opting for intrauterine device were allocated to placement within 48 hours of complete medical abortion (intervention group) or at 2-4 weeks after abortion (control group). We defined the abortion as complete after bleeding of clots and cessation of heavy bleeding following use of misoprostol. Patients answered questionnaires at 3, 6 and 12 months. Primary outcome was use of intrauterine device at 6 months post abortion. Secondary outcomes included expulsion rate, pain at placement, adverse events and complications from the abortion, acceptability, and pregnancies and their outcomes. Differences in non-parametric continuous variables were analyzed by the Mann-Whitney U-test and differences in dichotomous variables were analyzed by Chi square test or Fisher’s exact test. A p-value of < 0.05 was considered statistically significant.

Results
In the intervention group, 91/111 (82%) used an intrauterine device at six months after the abortion, compared to 87/112 (77.7%) in the control group with a difference in proportion of 4.3% (95% CI -0.062, 0.148, p=0.51). Attendance rate and rate of successful intrauterine device placement were similar between groups. Patients in the intervention group had lower pain scores at placement of the intrauterine device (mean pain score VAS 32.3, SD 29) compared to the control group (mean pain score VAS 43.4, SD 27.9, p=0.002). Patients preferred their allocated time of placement significantly more often in the intervention group, (83/111, 74.8%) compared to the control group (70/114, 61.4%, p=0.03). Use of ultrasound at intrauterine device placement (because of doubts concerning complete abortion) was more common in the intervention group (43/108, 39.8%) compared to the control group (15/101, 14.9%, p<0.001) and in one patient in the control group, a retained gestational sac was found. Three patients in the intervention group and two patients in the control group had a vacuum aspiration. No difference was found in intrauterine device expulsion rates between the groups. In the intervention group, 9/97 (9.3%) patients experienced expulsion during the first six months after abortion and 4/89 (4.5%, p=0.25) 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 ≤ 63 days’ gestation does not lead to higher user rates at six months after the abortion, compared with intrauterine device placement at 2-4 weeks after abortion. When compared with placement at a follow-up visit after 2-4 weeks, intrauterine device placement within 48 hours after early medical abortion appears safe, is preferred by patients and associated with lower pain scores.
Keywords

Abortion, Induced
Contraception
Family Planning Services
Intrauterine Devices, Copper
Intrauterine Devices, Medicated
IUD, Hormone Releasing
Long-Acting Reversible Contraception
Postabortion intrauterine device insertion


1. 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). Because fertility may return already 8-10 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. 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 one previous abortion.

Intrauterine devices are safe, well tolerated and known to reduce the risk of unwanted pregnancies and subsequent need for abortions. In order to increase access to immediate use of contraception after pregnancy, placement of an IUD at the time of cesarean section or after vaginal birth is routinely performed in many settings today. Infection and expulsion rates are low after planned cesarean section whereas expulsion rates are considerably higher after vaginal birth. IUD placement at the time of first-trimester surgical abortion is well studied and regarded as convenient, safe, and effective. 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 post-abortion contraception. 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 two to four weeks after a medical abortion. In Sweden, the current recommendation is to place IUDs after medical abortion within one week of misoprostol administration. However, adherence to this guideline is low. Patients who miss this follow-up visit risk being left without contraception.
Previous trials have examined the effectiveness and safety of IUD placement after medical abortion within one week of mifepristone administration or at a later time point. However, these trials have been performed with an ultrasound examination prior to IUD placement as part of the protocol. These studies have shown similar expulsion rates with earlier and later times of placement and that post abortion 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.

In addition to these studies, Korjamo et al performed an RCT with placement of a hormonal IUD within 3 days of Misoprostol administration or at 2-4 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 there are, to our knowledge, no previous study on placement of IUD as early as within 48 hours after complete abortion without routine use of ultrasound after early medical abortion. The aim of this randomized controlled trial was to compare the rate of IUD use at 6 months following medical abortion up to 63 days’ gestation where an IUD was placed either within 48 hours after complete abortion or at 2-4 weeks after abortion. We hypothesized that placement of IUD early after medical abortion would lead to placement rates close to 100 percent. Furthermore, we expected that early placement would increase the long-term use of IUD with maintained safety and patient satisfaction.
2. Materials and Methods

The design was an open-label, randomized, controlled, multicenter, superiority trial (phase 3). We recruited patients ≥18 years requesting medical abortion with gestation ≤63 days and opting for post abortion IUD at the gynecology clinics of Danderyd, Stockholm South General, Falun/Mora, Uppsala, 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 >1000ml, 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 post abortion 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 at intake of mifepristone, to placement of an IUD within 48 hours after complete abortion (intervention group) or to IUD placement at a scheduled follow-up visit 2-4 weeks after abortion according to routine care (control group). The abortion was defined as complete after patients reporting bleeding of clots and cessation of heavy bleeding following use of misoprostol and the providers finding no reason to suspect an incomplete abortion, based on patients’ history. To confirm complete abortion, all patients took a low sensitivity urine pregnancy test at 2-4 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 4-8. 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 Medical products agency (EudraCT number 2018-000287-29).

The medical termination of pregnancy was carried out according to the WHO guidelines. We performed a Chlamydia PCR-test, unless the patient actively abstained, and screening for bacterial vaginosis using Amsel’s criteria. Patients with bacterial vaginosis received treatment started prior to 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 two to four weeks. The study drugs approved for this study were: Mirena (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 below the age of 26 normally pay a sum corresponding to approximately 10 UDS/Euros for the device. Women above 25 years of age pay approximately 95 USD for the hormonal IUDs used in this study. The placement visit is always provided for free within the health care 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, three 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 six months post abortion, evaluated as the proportion of patients using IUD versus not using IUD. The secondary outcomes were rates of IUD placement at allocated time, reasons for non-placement of IUD, expulsion rate, pain at placement, adverse events and complications from the abortion, acceptability, 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 0-100 where 0 is equal to no pain and 100 is equal 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 six months after abortion would be at least 20 percent higher in the intervention group. The sample size was calculated based on the hypothesis of 80 percent IUD use in the intervention group and 60 percent use in the control group at six
months after abortion. Three to five percent were estimated to need a vacuum aspiration due
to incomplete abortion and/or prolonged bleeding, and approximately 15 percent loss to
follow-up was expected, which is commonly seen in abortion studies. With a power of 90
percent and an alpha of 0.05, we needed to randomize 240 patients. An interim analysis was
performed when 50 percent of patients had been recruited, with the predefined decision to
stop inclusion in case of expulsion rates exceeding 20 percent or acceptability rates below 50
percent at the 3-month follow-up in any group.

We performed statistical analyses using IBM SPSS Statistics for Windows, version 26 (IBM,
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 the 6-month follow-up. 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.
Non-parametric continuous variables are presented as medians with minimum and maximum
values; differences between groups were analyzed by the Fisher’s exact test. Dichotomous
variables are presented as proportions with differences between groups analyzed by the Chi²
test or Fisher’s exact test, as appropriate. All differences between groups were considered as
statistically significant if they had a p-value <0.05.

3. Results

From January 2019 to February 2021, a total of 240 patients having early medical abortion up
to 63 days’ gestation and opting for IUD post abortion were included in the trial. The flow of
patients is described in Figure 1. In all, 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 2-4 weeks. Of these, 92 (76.7%) received the allocated intervention. Three patients were excluded in the intervention group due to withdrawal of consent (n=2) or not having an abortion (n=1). In the control group, three patients withdrew consent. The groups were comparable regarding baseline characteristics and IUDs chosen (Table 1).

This report includes analysis of primary outcome at 6 months and secondary outcomes at this time point 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 where 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, 91/111 (82%) used an IUD at six months after the abortion, compared to 87/112 (77.7%) in the control group with a difference in proportion of 4.3% (95% CI -0.062, 0.148, p=0.51). 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, 108/117 (92.3%) patients attended the IUD placement visit. IUDs in the intervention group were placed at a median of 42 hours (IQR 21-46 hours, minimum 0 and maximum 144 hours) after completed abortion and all but one placement were successful. The failure was due to severe pain and inability to pass the IUD through the internal cervical os. The patient declined another try with anesthetics and at six months post abortion, she used condom as contraception. In the control group, 103/118 (87.3%) patients attended the IUD placement visit. There were three failed placements. Two were due to severe pain and the third one was due to signs of infection. Of the two patients with severe pain at placement, one
had an IUD inserted in general anesthesia later on, but then withdrew consent to continue participation. The other patient withdrew consent when contacted at the three-month follow-up. The patient with signs of infection had an IUD inserted later on, but became pregnant with an ectopic pregnancy (see 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 84/97 (86.6%) in the intervention group and 79/89 (88.8%) in the control group (p=0.82).

Use of ultrasound at IUD placement was more common in the intervention group compared to the control group (p<0.001). In the intervention group, ultrasound was used in 43/108 (39.8%) patients. There were no patients with retained products of conception. In the control group, ultrasound was used in 15/101 (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, SD 29) compared to the control group (mean pain score VAS 43.4, SD 27.9, p=0.002). A description of pain scores at different points of measurement is shown in figure 2.

Health care providers rated the ease of IUD placement as very easy/easy/neither easy nor difficult in 106/108 (98.1%) of the patients in the intervention group and
difficult in 2/108 patients (1.9%). Corresponding numbers in the control group were 93/101 (92.1%) and 8/101 (7.9%) respectively (p=0.05). Patients preferred their allocated time of IUD placement significantly more often in the intervention group, (83/111, 74.8%) compared to the control group (70/114, 61.4%, p=0.03).

A total of three patients in the intervention group had a vacuum aspiration after the medical abortion due to retained products of conception. In the control group, two 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). In the intervention group, 10/111 (9.0%) patients experienced IUD expulsion during the first six months after abortion (seven parous and three nulliparous patients) and 4/112 (3.6%, p=0.11) in the control group (two parous and two nulliparous patients). At six months after the abortion, four 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=0.25, Table 3).

Within three months after the abortion, one 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 3-6 months after the abortion, four patients in the intervention group and three patients in the control group became pregnant. Among the patients in the intervention group, one 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 due to side effects. At the 6-month follow-up, none of these two patients had decided how to proceed with the pregnancy. In the control group, the patient with an ectopic pregnancy at three 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 due to side effects, became pregnant again and had a miscarriage.

4. Comment

a. Principal Findings

Placement of an IUD within 48 hours after complete abortion with ≤63 days’ gestation does lead to higher user rates six months after the abortion compared with IUD placement at 2-4 weeks after abortion. When compared with placement at a follow-up visit after 2-4 weeks, IUD placement within 48 hours after early medical abortion appears safe and is preferred by patients and associated with lower pain scores.

b. 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 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 2-4 weeks after the abortion. In the Sääv study, women were randomized to IUD placement 5-9 days or 3-4 weeks after mifepristone administration. Both these prospective studies had attendance rates above 85% with follow-up at the abortion clinic. In contrast, Pohjoranta (study also performed in Finland) retrospectively found that 57% of patients attended follow-up at a primary health care
center. These results support the positive impact of scheduled follow-ups, preferably at the abortion clinic.

Sääv et al reported continued use of intrauterine devices at 68% in the intervention group and 72% in the delayed group. In 2011, Shimoni et al studied IUD use in patients in New York, USA, randomized to placement of a copper-IUD within one week of mifepristone administration compared to 4-6 weeks after medical abortion. They reported a non-statistical difference with 69% use after 6 months in the intervention group and 60% in the control group. Korjamo et al did not report IUD use at 6 months but at one 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 one year to be compared with 82% in the intervention group and 77.7% in the control group at 6 months post abortion in our study.

Expulsion rate of IUDs in the control group in our study is comparable to previous studies with placement of IUDs within two to four weeks after abortion. In contrast, in the intervention group of our study, the 9.3% expulsion rate at 6 months post-abortion is lower than the 12.5% expulsion rate at 3 months found by Korjamo et al. However, a majority of the 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 to Sääv et al. However, in that study the time of expulsion in relation to placement was not reported, nor did they differ between partial and total expulsion. Studies have not been able to show that ultrasound prior to IUD placement can predict risk of expulsion. We actively chose not to include an ultrasound examination as part of our follow-up protocol to increase generalizability. In our study, ultrasound examinations did not show
any retained products of conception. Thus, our results are reassuring concerning safety of early placement of IUD after medical abortion without prior ultrasound examination. All patients had a low sensitivity pregnancy test for confirmation of abortion completion according to guidelines.

One hypothesis that has previously not been explored was that immediate IUD placement would be less painful than delayed placement due to dilation of the cervix after the abortion. We measured pain scores momentarily on a visual analogue scale and results clearly showed that patients in the intervention group had significantly lower pain scores during IUD placement compared to patients in the control group.

c. 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 be due to minimal cervical dilation in early medical abortion. Early placement is preferred by patients and results in lower pain scores than placement after 2-4 weeks post abortion. We hypothesize that the lower pain scores are related to the naturally dilated cervix postabortion. We see 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. There are no concerns about implementation of these practices into guidelines and clinical practice.
d. Research Implications

This study reports the primary outcome and secondary outcomes of our trial at 6 months 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 IUD after medical abortion remains to be explored.

e. Strengths and Limitations

The strength of this study is the robust randomized controlled trial design. It was not deemed feasible to blind participants. The study size was larger than 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 cannot 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 post abortion 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 may also 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.

f. Conclusions

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

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Table 1. Baseline characteristics

<table>
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<th>Demographic characteristics</th>
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<th>Control (n=120)</th>
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<td>1</td>
</tr>
<tr>
<td><strong>Other baseline characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gestational age at mifepristone intake</td>
<td>43</td>
<td>42</td>
</tr>
<tr>
<td>Median</td>
<td>40-51.25</td>
<td>38-49.75</td>
</tr>
<tr>
<td>IQR</td>
<td>28-68</td>
<td>28-63</td>
</tr>
<tr>
<td>Min-max</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Parous women n (%)</td>
<td>88 (73.3)</td>
<td>84 (70)</td>
</tr>
<tr>
<td>Previous abortion n (%)</td>
<td>72 (60.5)</td>
<td>72 (60)</td>
</tr>
<tr>
<td>Misoprostol taken at home n (%)</td>
<td>104 (87.4)</td>
<td>101 (84.2)</td>
</tr>
<tr>
<td>Type of IUD placed n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mirena</td>
<td>59 (54.6)</td>
<td>45 (44.1)</td>
</tr>
<tr>
<td>Kyleena</td>
<td>39 (36.1)</td>
<td>49 (48)</td>
</tr>
<tr>
<td>Jaydess</td>
<td>3 (2.8)</td>
<td>1 (1.0)</td>
</tr>
<tr>
<td>Copper-IUD Nova T</td>
<td>7 (6.5)</td>
<td>7 (6.9)</td>
</tr>
<tr>
<td>IUD not placed</td>
<td>12</td>
<td>18</td>
</tr>
</tbody>
</table>

IQR= inter quartile range, IUD= intrauterine device

Baseline characteristics of patients having medical abortion up to 63 days’ gestation and opting for intrauterine device as postabortion contraception (N=240)
Table 2. Proportion of patients using an intrauterine device at 6 months

<table>
<thead>
<tr>
<th></th>
<th>Intention to treat</th>
<th>Per protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention n=111</td>
<td>Control n=112</td>
</tr>
<tr>
<td>IUD use at 6 months n (%)</td>
<td>91 (82%)</td>
<td>87 (77.7%)</td>
</tr>
</tbody>
</table>

IUD = intrauterine device

Intervention = placement of an intrauterine device within 48 hours after early medical abortion

Control = placement of an intrauterine device at 2-4 weeks after early medical abortion

Proportions of patients using an intrauterine device at six months following early medical abortion (N=240). P-value calculated by Fisher’s exact test
Table 3. Expulsions of intrauterine devices

<table>
<thead>
<tr>
<th>Expulsion</th>
<th>Intervention</th>
<th>Control</th>
<th>P-value overall expulsions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Complete n (%)</td>
<td>Partial n (%)</td>
<td>Overall N (%)</td>
</tr>
<tr>
<td>Time post abortion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 3 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mITT</td>
<td>4/112 (3.6)</td>
<td>4/112 (3.6)</td>
<td>8/112 (7.1)</td>
</tr>
<tr>
<td>Per protocol</td>
<td>4/97 (4.1)</td>
<td>3/97 (3.1)</td>
<td>7/97 (7.2)</td>
</tr>
<tr>
<td>Between 3-6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mITT</td>
<td>2/111 (1.8)</td>
<td>0</td>
<td>2/111 (1.8)</td>
</tr>
<tr>
<td>Per protocol</td>
<td>2/97 (2.1)</td>
<td>0</td>
<td>2/97 (2.1)</td>
</tr>
<tr>
<td>Within 6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mITT</td>
<td>6/111 (5.4)</td>
<td>4/111 (3.6)</td>
<td>10/111 (9.0)</td>
</tr>
<tr>
<td>Per protocol</td>
<td>6/97 (6.2)</td>
<td>3/97 (3.1)</td>
<td>9/97 (9.3)</td>
</tr>
</tbody>
</table>

Expulsions of intrauterine devices within six months following medical abortion. P-values calculated by Fisher's exact test.

Figure legends

Figure 1. CONSORT 2010 Flow Diagram

Figure 2. Mean pain score during placement of intrauterine devices

References

1. HEIKINHEIMO O, GISLER M, SUHONEN S. Age, parity, history of abortion and contraceptive choices affect the risk of repeat abortion. Contraception 2008;78:149-54.


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


19. KORJAMO R, MENTULA M, HEIKINHEIMO O. Immediate versus delayed initiation of the levonorgestrel-releasing intrauterine system following medical termination of


Figure 1.

CONSORT 2010 Flow Diagram

**Enrollment**
- Assessed for eligibility (n=252)
  - Excluded (n=12)
    - Declined to participate (n=12)
- Randomized (n=240)

**Allocation**
- Allocated to intervention (n=120)
  - Received allocated intervention (n=103)
    - Gestational length above 63 days* (n=1)
    - Did not receive allocated intervention (n=17)
  - Did not have an abortion (n=1)
  - Withdraw consent before IUD insertion (n=2)
  - Failed insertion* (n=1)
  - Did not come for IUD insertion* (n=8)
  - Received IUD outside window* (n=4)
  - Insertion during surgical procedure* (n=1)
    - *Included in ITT analysis
- Allocated to control (n=120)
  - Received allocated intervention (n=92)
  - Did not receive allocated intervention (n=28)
  - Withdraw consent before IUD insertion (n=2)
  - Withdraw consent after surgical procedure (n=1)
  - Did not come for IUD insertion* (n=15)
  - Signs of infection at insertion* (n=1)
  - Received IUD outside window* (n=9)
    - *Included in ITT analysis

**Follow-Up**
- 3 months
  - Lost to follow-up (n=6)
    - Withdrew consent (n=1)
    - Could not be reached (n=5)*
      - *2/5 filled in the 6-month questionnaire
- 6 months
  - Lost to follow-up (n=2)
    - Withdrew consent (n=1)
    - Could not be reached (n=1)

**Analysis**
- Primary outcome
  - mITT analysis (n=111)
    - Excluded from analysis (n=9)
      - Withdrawals (n=5)
      - Could not be reached (n=4)
  - Per protocol analysis (n=97)
  - mITT analysis (n=112)
    - Excluded from analysis (n=8)
      - Withdrawals (n=4)
      - Could not be reached (n=4)
  - Per protocol analysis (n=89)
Figure 2. Mean pain score during placement of intrauterine devices

Error bars represent +/- 2 standard errors, * indicates significant difference