

# Better Contraceptive Choices: Should your intrauterine contraceptive be put in when you have an abortion over 12 weeks gestation, or a month afterwards?

<b>Submission date</b> 20/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/06/2010	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 28/10/2022	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Wendy V. Norman

### Contact details

200- 1177 West Broadway

Vancouver

Canada

V6H 1G3

+1 604 761 7767

wendy.norman@ubc.ca

## Additional identifiers

### Protocol serial number

N/A

## Study information

Scientific Title

# Better Contraceptive Choices for Marginalized Women: A Randomised Controlled Trial Comparing Immediate or Interval Insertion of Intrauterine Contraception after Second Trimester Abortion

## Study objectives

We hypothesize that intrauterine contraception (IUC) placed immediately after second trimester abortion will result in fewer pregnancies than current standard practice of intended placement at 4 weeks post-abortion.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The University of British Columbia, Children's and Women's Hospital Research Ethics Board (REB) approved on the 13th of April 2010 (ref: UBC Study ID: H10-00306)

## Study design

Interventional multisite randomized controlled trial. Randomization by blocking (4) and stratified for parity and study site.

## Primary study design

Interventional

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Contraceptive management; Intrauterine contraceptive devices

## Interventions

To women seeking a therapeutic abortion in their second trimester of pregnancy (over 12 weeks gestation) who are interested in intrauterine contraception, we offer a choice between two leading IUC devices currently available in Canada: LNG-IUC (containing 52 mg levonorgestrel, Mirena Intrauterine System, Bayer Inc, Toronto, Ont.) and CuT380-IUC (a T-shaped IUC offering 380mm<sup>2</sup> surface area of copper, FlexiT380 (+), Prosan International, BV).

The total duration of follow up is 5 years from the date of IUC insertion.

## Intervention Type

Other

## Phase

Not Applicable

## Primary outcome(s)

Pregnancy rate at one year among women randomized to immediate insertion compared to women randomized to a planned insertion at 4 weeks (interval insertion) for each of the two leading IUC devices.

As many women randomized to an interval insertion will never have an IUC inserted, a real life condition for this current standard of care, we will analyse pregnancy rates based upon those randomized to each group, rather than upon those who insert an IUC. In this way we will analyse

by intention to treat rather than by treatment received. Thus our primary outcome will reflect real life conditions and the true effectiveness of a health care delivery change to prevent unintended pregnancies (immediate insertions of IUC versus the current standard of planned interval insertions).

### **Key secondary outcome(s)**

1. Costs and cost effectiveness
2. Rates of loss to follow up
3. Adverse events (such as infection or perforation: anticipated at under 1%)
4. Expulsion
5. Continuation of method
6. Satisfaction with IUC chosen and with insertion timing assigned

These outcomes will be assessed initially at one year, and through questionnaires in this study and administrative data base access in subsequent studies, annually during the 5 year device effectiveness period.

### **Completion date**

06/04/2015

## **Eligibility**

### **Key inclusion criteria**

This study will be offered to all women who present at the study sites meeting all of the following criteria:

1. Have completed informed consent for an abortion over 12 and under 24 weeks gestational age
2. Have chosen an IUC (either LNG-IUS or CuT380-IUD) for contraception post abortion
3. Are residents of British Columbia (BC) registered with the Medical Services Plan health care system
4. Are able to give informed consent
5. No age limits. Women or girls of any age, fulfilling the above criteria will be eligible

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **Key exclusion criteria**

1. Any of the following contraindications to use of a LNG-IUC or a CuT380-IUC:
  - 1.1. Uterine cavity anomalies causing distortion of the endometrial canal including fibroids of > 5 cm, excluding repaired Uterine septum
  - 1.2. Current untreated PID, Chlamydia, gonorrhea, cervicitis or lower genital tract infection
  - 1.3. Wilsons Disease (if choosing a CuT380-IUC)
  - 1.4. Undiagnosed abnormal uterine bleeding

- 1.5. Known uterine or cervical malignancy or cervical dysplasia
- 1.6. Known or suspected progestin-dependent neoplasia, including breast cancer (if choosing a LNG-IUC)
- 1.7. Active liver disease or dysfunction (if choosing a LNG-IUC)
- 1.8. Actual benign or malignant liver tumours (if choosing a LNG-IUC)
- 1.9. Hypersensitivity to levonorgestrel or any of the other ingredients in the formulation or component of the container components of MIRENA (if choosing a LNG-IUC)
- 1.10. Current bacterial endocarditis
- 1.11. Established immunodeficiency
- 1.12. Acute malignancies affecting blood or leukemias
- 1.13. Recent trophoblastic disease while hCG levels are elevated
2. Intention to move from BC within the next year
3. Intention to conceive within the next year
4. Post Randomization Exclusion:
  - 4.1. Uterine perforation at the time of abortion
  - 4.2. Bleeding of more than 500 cc during abortion
  - 4.3. Any of the above exclusions detected at the time of abortion

**Date of first enrolment**

01/04/2010

**Date of final enrolment**

06/04/2015

## **Locations**

**Countries of recruitment**

Canada

**Study participating centre**

200- 1177 West Broadway

Vancouver

Canada

V6H 1G3

## **Sponsor information**

**Organisation**

University of British Columbia (Canada)

**ROR**

<https://ror.org/03rmrcq20>

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

Canadian Institutes of Health Research (CIHR) (Canada) (F09-04035)

**Alternative Name(s)**

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR\_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Canada

**Funder Name**

Women's Health Research Institute (Canada) (infrastructure support) (F08-05221)

**Funder Name**

Bayer Canada (solely by donation of Mirena devices with no financial support, nor input to study design or conduct) (F09-04254)

## Results and Publications

**Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	14/06/2011		Yes	No
<a href="#">Other publications</a>		12/07/2016	28/10/2022	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes

