

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

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

Study website
<http://www.bcc4me.ca>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a patient information sheet

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 380mm² 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 measure

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).

Secondary outcome measures

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.

Overall study start date

01/04/2010

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

Age group

Adult

Sex

Female

Target number of participants

716 women; 358 (175-Mirena IUS & 183-Copper) recruited to each arm: immediate insertion vs planned interval insertion. (Amended on 13/03/2012: participant enrollment completed)

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)

Sponsor details

Faculty of Medicine
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Sponsor type

University/education

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, 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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/06/2011		Yes	No
Other publications		12/07/2016	28/10/2022	Yes	No