ISRCTN19506752 https://doi.org/10.1186/ISRCTN19506752

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

Registration date
15/06/2010

Last Edited
28/10/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 ot girls of any age, fulfilling the above criteria will be eligibile

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
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Sponsor information

Organisation
University of British Columbia (Canada)

Sponsor details
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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