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A randomised trial of placement of Mirena at caesarean section or postpartum

Submission date	Recruitment status	[X] Prospectively registered
15/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/03/2016	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

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
A multicentre, randomised trial of placement of the Mirena, intrauterine contraceptive device at caesarean section or postpartum

Study objectives
Insertion of Mirena at time of caesarean section is a safe effective contraceptive option

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not available at time of registration

Study design
Multicentre randomised open-label pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

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

Interventions
Insertion of Mirena either at the time of elective caesarean section or at the usual time of 6 weeks postpartum with follow up until 6 months postpartum

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Expulsion of Mirena

For the group having Mirena inserted at the time of caesarean section, all outcomes will be measured 6 weeks, 3 months and 6 months after delivery.
For the group who have the Mirena inserted 6 weeks after delivery, primary and secondary outcomes will be measured 3 months and 6 months after delivery.

Secondary outcome measures
1. Breastfeeding rates and breastfeeding difficulties
2. Babies weight gain
3. Vaginal bleeding
4. Pelvic infection
5. Strings not visible
6. Uterine perforation
7. Malposition of the device within the cavity
8. Ovarian cysts
9. Pregnancy
10. Patient satisfaction
Data for most variables above will be categorical (yes or no).
Infant weight gain (g) and estimated number of days vaginal bleeding in the past month will be numeric.
Patient satisfaction will be rated 1-5, from very poor to excellent.

For the group having Mirena inserted at the time of caesarean section, all outcomes will be measured 6 weeks, 3 months and 6 months after delivery.
For the group who have the Mirena inserted 6 weeks after delivery, primary and secondary outcomes will be measured 3 months and 6 months after delivery.

Overall study start date
01/05/2010

Completion date
30/04/2011

Eligibility

Key inclusion criteria
Women having an elective caesarean section, who choose to use Mirena for contraception

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100

Key exclusion criteria

1. Suspected uterine infection
2. Uterine malformation
3. Cervical dysplasia

Date of first enrolment
01/05/2010

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
Australia

Study participating centre
Mackay Base Hospital
Mackay
Australia
4740

Sponsor information

Organisation
Mackay District of Queensland Health (Australia)

Sponsor details
c/o Dr David Farlow
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Sponsor type
Government

Website
http://www.health.qld.gov.au/mackay/default.asp

ROR
https://ror.org/00c1dt378

Funder(s)

Funder type
Government

Funder Name
Mackay District of Queensland Health (Australia)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2015		Yes	No