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Is two-dimensional ultrasound necessary six weeks after insertion of the 52-mg levonorgestrel-releasing intrauterine system (LNG-IUS) contraceptive?

Submission date
29/07/2021

Recruitment status
No longer recruiting

Registration date
07/09/2021

Overall study status
Completed

Last Edited
07/11/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The correct position of the contraceptive levonorgestrel intrauterine system (LNG-IUS) can be confirmed by two-dimensional ultrasound (2DUS). However, best the timing of a routine 2DUS to confirm the correct position is subject to discussion. The main aim of this study was to assess how often the LNG-IUS is found to be incorrectly positioned on 2DUS during routine investigation at six weeks after insertion in the gynecological outpatient department. Additionally, the study will investigate the relation between malposition of the LNG-IUS and clinical symptoms like unacceptable bleeding patterns and pelvic pain.

Who can participate?
Women seeking a 52mg LNG-IUS (Mirena®), over 18 years of age, for contraception or treatment of heavy menstrual bleeding.

What does the study involve?
2DUS was performed to check the position of the IUD immediately after insertion and six weeks later. Women were excluded if they did not attend the appointment for 2DUS six weeks after insertion. Women were asked to complete questionnaires six weeks after insertion and were asked about bleeding pattern and pelvic pain.

What are the possible benefits and risks of participating?
No additional benefits or risks to participants are anticipated.

Where is the study run from?
Máxima Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
May 2015 to December 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Patty van der Heijden, pattyvanderheijden@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
15.025

Study information

Scientific Title
Is two-dimensional ultrasound (2DUS) necessary six weeks after insertion of 52-mg LNG-IUS?

Study objectives
In this prospective cohort study we assessed the additional value of 2DUS six weeks after insertion. We described the frequency of malposition and the relationship between malposition of the LNG-IUS and clinical symptoms like bleeding pattern and/or pelvic pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/05/2015, Dagelijks Bestuur METC (Máxima Medisch Centrum, Locatie Veldhoven, Postbus 7777, 5500 MB Veldhoven; 3140-8888525; m.rutten@mmc.nl), ref: 15.025

Study design
Single-centre observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Diagnostics of malposition and complaints in women with 52-mg LNG-IUS

Interventions
Immediately after insertion of the LNG-IUS, the position of the LNG-IUS was assessed with the 2DUS by the resident, gynaecologist or physician assistant who performed the insertion. Six weeks after insertion a 2DUS was performed to evaluate the position of the LNG-IUS. Participants were asked to complete questionnaires 6 weeks after insertion. In the questionnaires women were asked about their bleeding pattern (presence of bleeding and/or spotting: 'no bleeding', 'regular menstruation', 'sometimes a day of spotting (maximum of once a week)', 'heavy menstrual bleeding', 'several days a week bleeding days', 'several days a week spotting days', 'continuously spotting', 'complete irregular cycle'). Women were asked to rate pelvic pain on a five-point Likert scale.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
levonorgestrel

Primary outcome(s)
Incidence of malposition on 2DUS during routine investigation six weeks after insertion

Key secondary outcome(s))
Clinical symptoms at six weeks:
1. Unacceptable bleeding pattern measured using a questionnaire
2. Pelvic pain measured using a 5-point Likert scale

Completion date
31/12/2018

Eligibility

Key inclusion criteria

1. Women who visited our clinic for the insertion of a 52mg LNG-IUS (Mirena®) for contraception or treatment of heavy menstrual bleeding
2. Over 18 years of age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
500

Key exclusion criteria
1. Presence of intracavitary polyps or fibroids on 2DUS prior to insertion
2. Unprotected intercourse one month prior to insertion if insertion took place outside menstruation
3. Women were excluded for analyses if no ultrasound was performed six weeks after insertion

Date of first enrolment
01/03/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Netherlands

Study participating centre
Máxima Medical Centre
de Run 4600
Veldhoven
Netherlands
5504DB

Sponsor information

Organisation
Máxima Medisch Centrum

ROR
https://ror.org/02x6rcb77

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. (pattyvanderheijden@gmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/10/2022	07/11/2023	Yes	No
Participant information sheet	In Dutch		10/08/2021	No	Yes
Protocol file	In Dutch		10/08/2021	No	No