# Clinical trial results:
# Immediate post partum LNG-IUS insertion or standard insertion procedure after childbirth
# An open-label, randomized, multicenter study

## Summary

| | |
|---|---|
| EudraCT number | 2017-001945-29 |
| Trial protocol | SE |
| Global end of trial date | 21 January 2021 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 29 March 2022 |
| First version publication date | 29 March 2022 |
| Summary attachment (see zip file) | Published article (Acta Obstet Gynecol Scand - 2022 - Lichtenstein Liljeblad - Effectiveness  safety and overall satisfaction of early-2.pdf) |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | 20170504 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Linköping University |
| Sponsor organisation address | University hospital, Linköping, Sweden, 58185 |
| Public contact | Jan brynhildsen, Linköping University, 46 101030000, jan.brynhildsen@liu.se |
| Scientific contact | Jan brynhildsen, Linköping University, 46 101030000, jan.brynhildsen@liu.se |

Notes:

**Paediatric regulatory details**

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Interim |
| Date of interim/final analysis | 31 March 2021 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 21 January 2021 |
| Global end of trial reached? | Yes |
| Global end of trial date | 21 January 2021 |
| Was the trial ended prematurely? | Yes |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective is to study if immediate insertion of LNG-IUS post-partum is non-inferior to golden standard (insertion six to eight weeks postpartum) with regard to unintended pregnancies measured as number of abortions.

Protection of trial subjects:

Possibility to directly contact study midwife (specific phone number) in case of questions or problems
Planned interim analysis after 100 requite patients to evaluate the rates of IUD expulsion and risk of unintended pregnancy
Contraceptive counseling for all women who ended participation

Background therapy:

Not relevant

Evidence for comparator:

No comparator. The study intended to compare different time points for LNG-IUS insertion post partum

| | |
|---|---|
| Actual start date of recruitment | 01 January 2018 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Sweden: 102 |
| Worldwide total number of subjects | 102 |
| EEA total number of subjects | 102 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 102 |

| | |
|---|---|
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

All pregnant women attending maternal health care at 4 centers will receive information of the study. The nurse-midwife will visit the delivery wards and once again inform the now delivered women of the study. Women who opt for a LNG-IUD for contraception post-partum and will give informed consent will then be randomized according to the protocol

### Pre-assignment

Screening details:

All pregnant women attending maternal health care at 4 centers will receive information of the study,). Each morning the study nurse-midwife will visit the delivery wards and once again inform the now delivered women of the study.

### Period 1

| | |
|---|---|
| Period 1 title | overall trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Immediate insertion |

Arm description:

Insertion of LNG-IUS with 48 hours post partum

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Mirena |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Intrauterine delivery system |
| Routes of administration | Intrauterine use |

Dosage and administration details:

52mg

| | |
|---|---|
| **Arm title** | Standard insertion |

Arm description:

Insertion of LNG-IUS 6-8 weeks post partum

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Mirena |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Intrauterine delivery system |
| Routes of administration | Intrauterine use |

Dosage and administration details:

52mg

| **Number of subjects in period 1[1]** | Immediate insertion | Standard insertion |
|---|---|---|
| Started | 52 | 49 |
| Completed | 52 | 49 |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: As far as I can see the number reports in the base line characteristic is also 101

## Baseline characteristics

### Reporting groups

| Reporting group title | overall trial |
|---|---|

Reporting group description: -

| Reporting group values | overall trial | Total | |
|---|---|---|---|
| Number of subjects | 101 | 101 | |
| Age categorical<br>Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 101 | 101 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| adults | 0 | 0 | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 101 | 101 | |
| Male | 0 | 0 | |

### Subject analysis sets

| Subject analysis set title | Interim/final |
|---|---|
| Subject analysis set type | Full analysis |

Subject analysis set description:

According to the study protocol an interim analysis should be performed after 100 included patients. he study was stopped according to predefined criteria. Consequently the interim analysis=the final analysis

| Reporting group values | Interim/final | | |
|---|---|---|---|
| Number of subjects | 101 | | |
| Age categorical<br>Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | | |
| Newborns (0-27 days) | 0 | | |
| Infants and toddlers (28 days-23 months) | 0 | | |
| Children (2-11 years) | 0 | | |
| Adolescents (12-17 years) | 0 | | |
| Adults (18-64 years) | 101 | | |
| From 65-84 years | 0 | | |
| 85 years and over | 0 | | |

| | | | |
|---|---|---|---|
| adults | 0 | | |

| | | | |
|---|---|---|---|
| Gender categorical<br>Units: Subjects | | | |
| Female | 101 | | |
| Male | 0 | | |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | Immediate insertion |
| Reporting group description: | |
| Insertion of LNG-IUS with 48 hours post partum | |
| Reporting group title | Standard insertion |
| Reporting group description: | |
| Insertion of LNG-IUS 6-8 weeks post partum | |
| Subject analysis set title | Interim/final |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| According to the study protocol an interim analysis should be performed after 100 included patients. he study was stopped according to predefined criteria. Consequently the interim analysis=the final analysis | |

### Primary: Proportions of abortions within one year after insertion of LNG-IUS.

| | |
|---|---|
| End point title | Proportions of abortions within one year after insertion of LNG-IUS.[1] |
| End point description: | |
| The primary objective is to study if immediate insertion of LNG-IUS post-partum is non-inferior to golden standard (insertion six to eight weeks postpartum) with regard to unintended pregnancies measured as proportion of women undergoing an abortion. | |
| End point type | Primary |
| End point timeframe: | |
| 12 months | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No pregnancy and consequently no abortion occurred in any arm.

| End point values | Immediate insertion | Standard insertion | Interim/final | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 52 | 49 | 101 | |
| Units: unintended pregnancies | | | | |
| number (not applicable) | | | | |
| pregnancy | 0 | 0 | 0 | |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

12 months

| | |
|---|---|
| Assessment type | Systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | ICD |
| Dictionary version | 10 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Immediate |
| Reporting group description: - | |
| Reporting group title | Standard |

Reporting group description: -

| Serious adverse events | Immediate | Standard | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 52 (3.85%) | 0 / 49 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Reproductive system and breast disorders | | | |
| Uterine perforation | Additional description: Two perforations occurred in the immediate group. Both detected after more than one year (after completion of the study) and required laparoscopy. Both patients recovered completely. | | |
| subjects affected / exposed | 2 / 52 (3.85%) | 0 / 49 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | Immediate | Standard | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 23 / 52 (44.23%) | 0 / 49 (0.00%) | |
| Reproductive system and breast disorders | | | |
| IUD expulsion | Additional description: In the early group 23/52 (44.2%) of hormonal IUDs were expelled,. No expulsions were detected in the standard group<br>Actually outcome and not AE | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 23 / 52 (44.23%) | 0 / 49 (0.00%) | |
| occurrences (all) | 23 | 0 | |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported