



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
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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 requisite 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
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Arm title	Immediate insertion
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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
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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			
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			
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			
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		
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Gender categorical			
Units: Subjects			
Female	101		
Male	0		

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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. The 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
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Dictionary used

Dictionary name	ICD
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Dictionary version	10
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Reporting groups

Reporting group title	Immediate
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Reporting group description: -

Reporting group title	Standard
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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 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