Clinical trial results:
Home abortion up to 10 weeks of gestation

Summary

EudraCT number	2013-004749-18
Trial protocol	SE
Global end of trial date	30 November 2021

Results information

Result version number	v1 (current)
This version publication date	23 February 2023
First version publication date	23 February 2023

Trial information

Trial identification

Sponsor protocol code	201311LM

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02191774
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Karolinska University Hospital
Sponsor organisation address	Solna, Stockholm, Sweden, 17176
Public contact	Lena Marions, Karolinska Institutet, 46 851776357, lena.marions@ki.se
Scientific contact	Lena Marions, Karolinska Institutet, 46 851776357, lena.marions@ki.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	Final
Date of interim/final analysis	15 August 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 November 2021
Global end of trial reached?	Yes
Global end of trial date	30 November 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate if medical abortion at home up to 10 weeks of gestation is as safe and acceptable as was previously shown for abortions in earlier pregnancies (<9 weeks of gestation).

Protection of trial subjects:

Participants were given instructions that emphasized the importance of contacting the clinic if any severe symptoms, which were thoroughly explained, would occur.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 November 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Sweden: 273
Worldwide total number of subjects	273
EEA total number of subjects	273

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)	273
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

We enrolled women seeking medical abortion up to 70 days of gestation from November 2014 to November 2021 from Södersjukhuset, Stockholm, Karolinska University Hospital, Stockholm, and some patients were also recruited from Sahlgrenska University Hospital, Göteborg and Helsingborg Hospital.

Pre-assignment

Screening details:

The inclusion criteria were ultrasound-confirmed intrauterine pregnancy up to 70 days of gestation, willingness to administer misoprostol at home, <18 years of age, haemoglobin higher than 100 g/L, ability to understand instructions, absence of any known health problems or clinical findings that could affect the patient's safety during the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Gestational age up to 63 days

Arm description:

This arm included women pregnant with a gestational age up to 63 days.

Arm type	Active comparator
Investigational medicinal product name	Mifegyn
Investigational medicinal product code	
Other name	Mifepristone
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

During the first visit to the abortion clinic, women swallowed 200 mg of mifepristone (Mifegyne, Exelgyn, Paris, France) on site.

Investigational medicinal product name	Misoprostol, Cytotec
Investigational medicinal product code	A02BB01
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Sublingual use, Vaginal use

Dosage and administration details:

After first visit and administration of Mifegyn, the women were provided with 1200 mcg of misoprostol (6 tablets of 0.2 mg of misoprostol Cytotec, Pfizer, Stockholm, Sweden). They were instructed to take four tablets of misoprostol vaginally at home 24-48 hours after mifepristone administration. In case of bleeding had not started within 3 hours after misoprostol administration, women were instructed to take additional two misoprostol tablets sublingually.

Arm title	Gestational age 64-70 days

Arm description:

This arm included women pregnant with a gestational age between 64 to70 days.

Arm type	Active comparator

Investigational medicinal product name	Mifegyn
Investigational medicinal product code	
Other name	Mifepristone
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

During the first visit to the abortion clinic, women swallowed 200 mg of mifepristone (Mifegyne, Exelgyn, Paris, France) on site.

Investigational medicinal product name	Misoprostol, Cytotec
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Number of subjects in period 1	Gestational age up to 63 days	Gestational age 64-70 days
Started	112	161
Completed	100	141
Not completed	12	20
Lost to follow-up	12	20

Baseline characteristics

Reporting groups	
Reporting group title	Gestational age up to 63 days
Reporting group description:	
This arm included women pregnant with a gestational age up to 63 days.	
Reporting group title	Gestational age 64-70 days
Reporting group description:	
This arm included women pregnant with a gestational age between 64 to70 days.	

Reporting group values	Gestational age up to 63 days	Gestational age 64-70 days	Total
Number of subjects	112	161	273
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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
median	28	29	
full range (min-max)	18 to 46	18 to 47	-
Gender categorical Units: Subjects			
Female	112	161	273

End points

End points reporting groups

Reporting group title	Gestational age up to 63 days
Reporting group description:	
This arm included women pregnant with a gestational age up to 63 days.	
Reporting group title	Gestational age 64-70 days
Reporting group description:	
This arm included women pregnant with a gestational age between 64 to70 days.	

Primary: Difference in mean complete abortion rate

End point title	Difference in mean complete abortion rate
End point description:	
The primary objective of the study was to study efficacy in gestations up to and above 63 days with home use of misoprostol. Efficacy was defined as a complete abortion without any need for surgical or medical intervention due to incomplete abortion or ongoing pregnancy.	
End point type	Primary
End point timeframe:	
14-28 days after the first appointment.	

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	100	141		
Units: Number of complete abortions	95	136		

Statistical analyses

Statistical analysis title	Difference in mean complete abortion rate
Statistical analysis description:	
Difference in mean complete abortion rate between gestational age up to 63 days vs gestational age 64-70 days.	
Comparison groups	Gestational age up to 63 days v Gestational age 64-70 days
Number of subjects included in analysis	241
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.745
Method	Wilcoxon (Mann-Whitney)

Secondary: Satisfied with the chosen treatment

End point title	Satisfied with the chosen treatment

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Number of women				
Agreeing with the statement	77	102		
Neutral	5	12		
Not agreeing with the statement	2	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Satisfied with the chosen treatment - Total score

End point title	Satisfied with the chosen treatment - Total score

End point description:

Total score 1-5.

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Score				
arithmetic mean (standard deviation)	4.6 (± 0.76)	4.42 (± 0.98)		

Statistical analyses

Statistical analysis title	Difference in mean Satisfied with the chosen treat
Comparison groups	Gestational age up to 63 days v Gestational age 64-70 days

Number of subjects included in analysis	202
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.247
Method	Wilcoxon (Mann-Whitney)

Secondary: Feeling calm and safe during the abortion

End point title	Feeling calm and safe during the abortion

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Number of women				
Agreeing with the statement	68	87		
Neutral	9	22		
Not agreeing with the statement	7	11		

Statistical analyses

No statistical analyses for this end point

Secondary: Feeling calm and safe during the abortion - Total score

End point title	Feeling calm and safe during the abortion - Total score

End point description:

Total score 1-5.

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Total score				
arithmetic mean (standard deviation)	4.11 (± 0.98)	3.92 (± 1.11)		

Statistical analyses

Statistical analysis title	Difference in Feeling calm & safe during abortion
Comparison groups	Gestational age 64-70 days v Gestational age up to 63 days
Number of subjects included in analysis	202
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.233
Method	Wilcoxon (Mann-Whitney)

Secondary: Provided with sufficient information before the abortion

End point title	Provided with sufficient information before the abortion

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Number of women				
Agreeing with the statement	78	106		
Neutral	5	9		
Not agreeing with the statement	1	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Provided with sufficient information before the abortion - Total score

End point title	Provided with sufficient information before the abortion - Total score

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Total score				
arithmetic mean (standard deviation)	4.62 (± 0.66)	4.48 (± 0.9)		

Statistical analyses

Statistical analysis title	Difference in Provided with sufficient information
Comparison groups	Gestational age up to 63 days v Gestational age 64-70 days
Number of subjects included in analysis	202
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.473
Method	Wilcoxon (Mann-Whitney)

Secondary: Treatment matching patient`s expectations

End point title	Treatment matching patient`s expectations

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Number of women				
Agreeing with the statement	68	90		
Neutral	10	14		
Not agreeing with the statement	5	15		

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment matching patient`s expectations - Total score

End point title	Treatment matching patient`s expectations - Total score

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Total score				
arithmetic mean (standard deviation)	4.19 (± 0.99)	3.95 (± 1.14)		

Statistical analyses

Statistical analysis title	Difference in Treatment matching expectations
Comparison groups	Gestational age up to 63 days v Gestational age 64-70 days
Number of subjects included in analysis	202
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.136
Method	Wilcoxon (Mann-Whitney)

Secondary: Experienced bleeding matching patient`s expectations

End point title	Experienced bleeding matching patient`s expectations

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Number of women				
Agreeing with the statement	31	60		
Neutral	33	39		
Not agreeing with the statement	20	21		

Statistical analyses

No statistical analyses for this end point

Secondary: Experienced bleeding matching patient`s expectations - Total score

End point title	Experienced bleeding matching patient`s expectations - Total score

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Total score				
arithmetic mean (standard deviation)	3.19 (± 1.25)	3.48 (± 1.11)		

Statistical analyses

Statistical analysis title	Difference in bleeding matching expactation
Comparison groups	Gestational age up to 63 days v Gestational age 64-70 days
Number of subjects included in analysis	202
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.1
Method	Wilcoxon (Mann-Whitney)

Secondary: Experienced pain matching patient`s expectations

End point title	Experienced pain matching patient`s expectations

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Number of women				
Agreeing with the statement	31	66		
Neutral	24	29		
Not agreeing with the statement	30	25		

Statistical analyses

No statistical analyses for this end point

Secondary: Experienced pain matching patient`s expectations - Total score

End point title	Experienced pain matching patient`s expectations - Total score

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Total score				
arithmetic mean (standard deviation)	2.98 (± 1.35)	3.52 (± 1.15)		

Statistical analyses

Statistical analysis title	Difference in experienced pain matching expectatio
Comparison groups	Gestational age up to 63 days v Gestational age 64-70 days

Number of subjects included in analysis	202
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.01
Method	Wilcoxon (Mann-Whitney)

Secondary: Provided with sufficient pain medication

End point title	Provided with sufficient pain medication

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Number of women				
Agreeing with the statement	74	102		
Neutral	7	11		
Not agreeing with the statement	2	7		

Statistical analyses

No statistical analyses for this end point

Secondary: Provided with sufficient pain medication - Total score

End point title	Provided with sufficient pain medication - Total score

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Total score				
arithmetic mean (standard deviation)	4.55 (± 0.84)	4.47 (± 1)		

Statistical analyses

Statistical analysis title	Difference in sufficient pain medication
Comparison groups	Gestational age up to 63 days v Gestational age 64-70 days
Number of subjects included in analysis	202
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.805
Method	Wilcoxon (Mann-Whitney)

Secondary: Recommendation of home abortion to a friend in the same situation

End point title	Recommendation of home abortion to a friend in the same situation

End point description:

End point type	Secondary

End point timeframe:

14-28 days after the first appointment.

End point values	Gestational age up to 63 days	Gestational age 64-70 days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	118		
Units: Number of women				
Agreeing with the statement	76	109		
Not agreeing with the statement	4	9		

Statistical analyses

Statistical analysis title	Difference in recommend home abortion to a friend
Comparison groups	Gestational age up to 63 days v Gestational age 64-70 days

Number of subjects included in analysis	202
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.467
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

During the study period, up to 14-28 days after the first appointment.

Assessment type	Systematic

Dictionary used

Dictionary name	Did not use any
Dictionary version	1

Reporting groups

Reporting group title	Overall group

Reporting group description: -

Serious adverse events	Overall group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 273 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Overall group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 273 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: The study has no SAEs or AEs. For example, incomplete abortion is the primary outcome and cannot be classified as AE. Nausea, vomiting is related to pregnancy and bleeding is included in the abortion.

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Limitation is the sample size, making it difficult to state that home abortion 64-70 days is as safe as >63 days. But available data on home abortion, our results strengthen the assumption that the efficacy is high also in pregnancies >63 days.

Notes: