Clinical trial results:
A Randomised Trial of First dose of Misoprostol Administration at Home or in Hospital for Medical Abortion between 12-22 gestational weeks - The PRIMA (PRIMing At home) Trial.

Summary

EudraCT number	2018-000964-27
Trial protocol	SE
Global end of trial date	28 February 2023

Results information

Result version number	v1 (current)
This version publication date	27 February 2025
First version publication date	27 February 2025

Trial information

Trial identification

Sponsor protocol code	WP2018

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Karolinska Institutet
Sponsor organisation address	Nobels väg 6, Solna, Sweden, 17165
Public contact	Kristina Gemzell Danielsson, Karolinska Institutet, 46 08517700002128, kristina.gemzell@ki.se
Scientific contact	Kristina Gemzell Danielsson, Karolinska Institutet, 46 08517700002128, kristina.gemzell@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	01 March 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 December 2022
Global end of trial reached?	Yes
Global end of trial date	28 February 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To compare the number of patients who are treated as day care patients in medical abortion from day 85 to day 153 of gestation when administrated the first dose of misoprostol at home or in the clinic

Protection of trial subjects:

All participants were given oral and written information about the study, had the opportunity to ask questions, and signed written informed consent before random assignment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 January 2019
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: 457
Worldwide total number of subjects	457
EEA total number of subjects	457

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)	457
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

People who sought induced abortion care at the abortion clinic of the respective study site were asked to participate if they fulfilled the inclusion criteria and had no exclusion criteria.

Pre-assignment

Screening details:

People who sought induced abortion care at the abortion clinic of the respective study site were asked to participate if they fulfilled the inclusion criteria and had no exclusion criteria.

Period 1

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

Blinding implementation details:

The allocation groups were unmasked for data entrants. While performing the statistical analysis, the groups were masked to the researcher.

Arms

Are arms mutually exclusive?	Yes
Arm title	Home - use

Arm description:

Home administration of the first dose of misoprostol

Arm type	Experimental
Investigational medicinal product name	Cytotec
Investigational medicinal product code	
Other name	misoprostol
Pharmaceutical forms	Vaginal tablet
Routes of administration	Vaginal use

Dosage and administration details:

Between 24–48 h after taking mifepristone, the participants in the home treatment group administered the first dose of misoprostol (800 µg) deep vaginally at home, together with pain medication, and returned to the hospital 2 h later to receive the remaining treatment in hospital.

Arm title	Hospital

Arm description:

Hospital administration of the first dose of misoprostol

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1[1]	Home - use	Hospital
Started	220	215
Completed	214	215
Not completed	6	0
Protocol deviation	6	-

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: 457 participants were initially enrolled - 228 assigned to home treatment, however 8 were excluded prior to treatment - 229 were assigned to hospital treatment but 14 were excluded prior to treatment.

Baseline characteristics

Reporting groups	
Reporting group title	Home - use
Reporting group description:	
Home administration of the first dose of misoprostol	
Reporting group title	Hospital
Reporting group description:	
Hospital administration of the first dose of misoprostol	

Reporting group values	Home - use	Hospital	Total
Number of subjects	220	215	435
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			
arithmetic mean	31.5	31.2	
standard deviation	± 6.0	± 6.1	-
Gender categorical			
Units: Subjects			
Female	220	215	435
Male	0	0	0

End points

End points reporting groups	
Reporting group title	Home - use
Reporting group description:	
Home administration of the first dose of misoprostol	
Reporting group title	Hospital
Reporting group description:	
Hospital administration of the first dose of misoprostol	

Primary: Treated as day-care patient (<9 h)	
End point title	Treated as day-care patient (<9 h)
End point description:	
End point type	Primary
End point timeframe:	
Per protocol	

End point values	Home - use	Hospital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	220	215		
Units: Participants	156	99		

Statistical analyses

Statistical analysis title	Differences in group means with 95% confidence int
Statistical analysis description:	
We presented primary and secondary outcomes as differences in group means with 95% confidence interval (CI) for continuous variables and as differences in group percentages with 95% CI for dichotomous variables.	
Comparison groups	Home - use v Hospital
Number of subjects included in analysis	435
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Chi-squared
Parameter estimate	Mean difference (final values)
Point estimate	24.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.4
upper limit	34.3

Variability estimate	Standard deviation

Secondary: Completed abortion rate at 24 h

End point title	Completed abortion rate at 24 h

End point description:

End point type	Secondary

End point timeframe:

Per protocol

End point values	Home - use	Hospital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	219	212		
Units: Participants	198	191		

Statistical analyses

Statistical analysis title	Differences in group means
Comparison groups	Home - use v Hospital
Number of subjects included in analysis	431
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Chi-squared
Parameter estimate	Mean difference (final values)
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.4
upper limit	5.7
Variability estimate	Standard deviation

Secondary: Hours in clinic from admission to discharge

End point title	Hours in clinic from admission to discharge

End point description:

End point type	Secondary

End point timeframe:

Per protocol

End point values	Home - use	Hospital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	219	211		
Units: hour				
arithmetic mean (standard deviation)	10.3 (± 10.8)	13.1 (± 12.5)		

Statistical analyses

Statistical analysis title	Differences in group means
Comparison groups	Home - use v Hospital
Number of subjects included in analysis	430
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.014
Method	Chi-squared
Parameter estimate	Mean difference (final values)
Point estimate	-2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	-0.6
Variability estimate	Standard deviation

Secondary: Induction to fetal abortion interval (min)

End point title	Induction to fetal abortion interval (min)
End point description:	
End point type	Secondary
End point timeframe:	
Per protocol	

End point values	Home - use	Hospital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	218	211		
Units: minute				
arithmetic mean (standard deviation)	494.1 (± 511.0)	493.1 (± 553.5)		

Statistical analyses

Statistical analysis title	Differences in group means
Comparison groups	Home - use v Hospital
Number of subjects included in analysis	429
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.98
Method	Chi-squared
Parameter estimate	Mean difference (final values)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-100.1
upper limit	102
Variability estimate	Standard deviation

Secondary: Number of doses of misoprostol used	
End point title	Number of doses of misoprostol used
End point description:	
The loading dose equals four tablets of misoprostol (800 µg), and the following doses equal two tablets per dose.	
End point type	Secondary
End point timeframe:	
Per protocol	

End point values	Home - use	Hospital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	218	211		
Units: number of doses				
arithmetic mean (standard deviation)	2.92 (± 1.71)	2.93 (± 1.79)		

Statistical analyses

Statistical analysis title	Differences in group means
Comparison groups	Home - use v Hospital

Number of subjects included in analysis	429
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.92
Method	Chi-squared
Parameter estimate	Mean difference (final values)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.3
Variability estimate	Standard deviation

Secondary: Satisfaction with abortion treatment

End point title	Satisfaction with abortion treatment
End point description:	
End point type	Secondary
End point timeframe:	
Per protocol	

End point values	Home - use	Hospital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	188		
Units: Participants				
1 (very disappointed)	0	1		
2--	0	3		
3--	4	4		
4--	25	28		
5 (very satisfied)	171	152		

Statistical analyses

Statistical analysis title	Differences in group means
Comparison groups	Home - use v Hospital
Number of subjects included in analysis	388
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.078
Method	Chi-squared

Secondary: Preference of first misoprostol administration

End point title	Preference of first misoprostol administration

End point description:

End point type	Secondary

End point timeframe:

Per protocol

End point values	Home - use	Hospital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	188		
Units: Participants				
Home	155	96		
Hospital	45	92		

Statistical analyses

Statistical analysis title	Differences in group means
Comparison groups	Home - use v Hospital
Number of subjects included in analysis	388
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Chi-squared

Secondary: Pain at admission (VAS)

End point title	Pain at admission (VAS)

End point description:

End point type	Secondary

End point timeframe:

At admission

End point values	Home - use	Hospital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	193	175		
Units: millimetre(s)				
arithmetic mean (standard deviation)	28.4 (± 26.0)	5.83 (± 13.19)		

Statistical analyses

Statistical analysis title	Differences in group means
Comparison groups	Home - use v Hospital
Number of subjects included in analysis	368
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Chi-squared
Parameter estimate	Mean difference (final values)
Point estimate	22.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.4
upper limit	26.7
Variability estimate	Standard deviation

Secondary: Pain at abortion (VAS)

End point title	Pain at abortion (VAS)

End point description:

End point type	Secondary

End point timeframe:

At abortion

End point values	Home - use	Hospital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	164	150		
Units: millimetre(s)				
arithmetic mean (standard deviation)	39.7 (± 35.1)	39.0 (± 33.9)		

Statistical analyses

Statistical analysis title	Differences in group means
Comparison groups	Hospital v Home - use
Number of subjects included in analysis	314
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.87
Method	Chi-squared
Parameter estimate	Mean difference (final values)
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7
upper limit	8.3
Variability estimate	Standard deviation

Secondary: Surgical interventions needed	
End point title	Surgical interventions needed
End point description:	
End point type	Secondary
End point timeframe:	
At time of abortion	

End point values	Home - use	Hospital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	219	212		
Units: Participants	14	18		

Statistical analyses

Statistical analysis title	Differences in group means
Comparison groups	Home - use v Hospital
Number of subjects included in analysis	431
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.52
Method	Chi-squared
Parameter estimate	Mean difference (final values)
Point estimate	-2.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.5
upper limit	3.3
Variability estimate	Standard deviation

Adverse events

Adverse events information

Timeframe for reporting adverse events:

08Jan2019 to 28Mar2023

Assessment type	Systematic

Dictionary used

Dictionary name	TBU
Dictionary version	unk

Reporting groups

Reporting group title	All study subjects.

Reporting group description: -

Serious adverse events	All study subjects.		
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 435 (2.76%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Blood and lymphatic system disorders			
Bleeding			
subjects affected / exposed	11 / 435 (2.53%)		
occurrences causally related to treatment / all	1 / 11		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Infection			
subjects affected / exposed	1 / 435 (0.23%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	All study subjects.		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	97 / 435 (22.30%)		
Pregnancy, puerperium and perinatal conditions			
Retention of products of conception and expulsion of fetus before admission	Additional description: Retention of products of conception and expulsion of fetus before admission		

subjects affected / exposed occurrences (all)	27 / 435 (6.21%) 27		
Blood and lymphatic system disorders Bleeding subjects affected / exposed occurrences (all)	 58 / 435 (13.33%) 58		
General disorders and administration site conditions Other subjects affected / exposed occurrences (all)	 16 / 435 (3.68%) 16		
Immune system disorders Allergy subjects affected / exposed occurrences (all)	 1 / 435 (0.23%) 1		
Infections and infestations Infection subjects affected / exposed occurrences (all)	 20 / 435 (4.60%) 20		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 January 2021	Addition of two new study sites Exact date unknown, year 2021 correct.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/39216976