



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 to 70 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.

| | |
|--|-----------------------------|
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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 to 70 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 (\pm 0.76) | 4.42 (\pm 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 (\pm 0.98) | 3.92 (\pm 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 (\pm 0.99) | 3.95 (\pm 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 (\pm 1.25) | 3.48 (\pm 1.11) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Difference in bleeding matching expectation |
| 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 (\pm 0.84) | 4.47 (\pm 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: