



Clinical trial results:

Impact of luteal phase support with vaginal progesterone on the clinical pregnancy rate in IUI cycles stimulated with gonadotrophins: a prospective randomized multicentre study.

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2010-023867-17 |
| Trial protocol | BE |
| Global end of trial date | 22 October 2015 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 14 February 2021 |
| First version publication date | 14 February 2021 |
| Summary attachment (see zip file) | Publication (2010-023867-17 publication.pdf) |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | S52775 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01826747 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | UZLeuven |
| Sponsor organisation address | Herestraat 49, Leuven, Belgium, 3000 |
| Public contact | Karen Peeraer, UZLeuven, +32 16343650, karen.peeraer@uzleuven.be |
| Scientific contact | Karen Peeraer, UZLeuven, +32 16343650, karen.peeraer@uzleuven.be |

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 | 22 October 2015 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 22 October 2015 |
| Global end of trial reached? | Yes |
| Global end of trial date | 22 October 2015 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

Test the hypothesis that luteal phase support with vaginal progesterone leads to a higher clinical pregnancy rate when compared to no luteal phase support in a program of intrauterine insemination after controlled ovarian stimulation with gonadotrophins

Protection of trial subjects:

No measurements were taken. Study did not cause additional pain or distress.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 01 April 2011 |
| 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 | Belgium: 393 |
| Worldwide total number of subjects | 393 |
| EEA total number of subjects | 393 |

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) | 393 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

All couples with an indication for intrauterine insemination (IUI) such as unexplained infertility, mild male factor infertility, or minimal/mild endometriosis were eligible for this study during their first IUI cycle. Before their inclusion in the study, all couples underwent a complete infertility evaluation.

Pre-assignment

Screening details:

first IUI cycle

Physical examination, medical history check

serum hormone assay between day 2 and 5 of menstrual cycle

pelvic ultrasound

assessment of

tubal patency either by hysterosalpingography or laparoscopy, and semen analysis

<43 years old, BMI = <30

at least

one patent tube

partner sperm motile of ≥ 5 million

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 | control group without luteal phase support |

Arm description:

control group: standard of care intrauterine insemination

| | |
|----------|-----------------|
| Arm type | No intervention |
|----------|-----------------|

No investigational medicinal product assigned in this arm

| | |
|------------------|---------------------------------------|
| Arm title | study group with luteal phase support |
|------------------|---------------------------------------|

Arm description:

study group with luteal phase support. Vaginal progesterone gel used

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | Crinone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Gel |
| Routes of administration | Vaginal use |

Dosage and administration details:

once daily in the morning starting on the day after IUI until the time of pregnancy test (b-hCG) about 15 days after IUI. Crinone was administered by an applicator that delivered 1.125 g of vaginal gel containing 90 mg of progesterone.

| Number of subjects in period 1 | control group without luteal phase support | study group with luteal phase support |
|--------------------------------|--|--|
| | | |
| Started | 191 | 202 |
| Completed | 177 | 187 |
| Not completed | 14 | 15 |
| Physician decision | 6 | 3 |
| Pregnancy | 5 | 7 |
| patient decision | 2 | 4 |
| Protocol deviation | 1 | 1 |

Baseline characteristics

Reporting groups

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

Reporting group description: -

| Reporting group values | overall trial | Total | |
|--|---------------|-------|--|
| Number of subjects | 393 | 393 | |
| Age categorical | | | |
| Female subjects age: 18-42 year | | | |
| 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) | 0 | 0 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Female 18-42 years | 393 | 393 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 393 | 393 | |
| Male | 0 | 0 | |

End points

End points reporting groups

| | |
|--|--|
| Reporting group title | control group without luteal phase support |
| Reporting group description: control group: standard of care intrauterine insemination | |
| Reporting group title | study group with luteal phase support |
| Reporting group description: study group with luteal phase support. Vaginal progesterone gel used | |

Primary: Clinical pregnancy rate

| | |
|------------------------|--|
| End point title | Clinical pregnancy rate ^[1] |
| End point description: | |

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Primary endpoint is clinical pregnancy rate. 34 of the 202 patients in the study group became pregnant (16.8%). 21 of the 191 patients in the control group became pregnant (11%)

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: not specified in publication

| End point values | control group without luteal phase support | study group with luteal phase support | | |
|-----------------------------|--|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 191 | 202 | | |
| Units: 34 | 21 | 34 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Safety was not an endpoint of the study.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 14.0 |
|--------------------|------|

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

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: adverse events not collected

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/27565253>