



Clinical trial results:

A pharmacokinetic study of vaginally and intravenously administered oxytocin in postmenopausal women with vaginal atrophy

Summary

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|--------------------------|----------------|
| EudraCT number | 2013-002690-22 |
| Trial protocol | SE |
| Global end of trial date | 30 April 2014 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 17 July 2020 |
| First version publication date | 17 July 2020 |
| Summary attachment (see zip file) | Summary of study OXYPEP003 (Summary of study OXYPEP003.pdf) Report of study OXYPEP003 (Report Pharmacokinetic study + Study Synopsis OXYPEP003.pdf) |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | OXYPEP003 |
|-----------------------|-----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Peptonic Medical AB |
| Sponsor organisation address | Gustavslundsvagen 143, Bromma, Sweden, 167 51 |
| Public contact | Dan Markusson, PeP-Tonic Medical AB, +46 768550200, info@peptonicmedical.se |
| Scientific contact | Dan Markusson, PeP-Tonic Medical AB, +46 768550200, dan.markusson@peptonicmedical.se |

Notes:

Paediatric regulatory details

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|--|----|
| 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 | 26 August 2014 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 30 April 2014 |
| Global end of trial reached? | Yes |
| Global end of trial date | 30 April 2014 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the uptake of oxytocin following intravaginal administration of Vagitocin 400IU over a period of 14 days and also to compare oxytocin bioavailability after vaginal and intravenous administration

Protection of trial subjects:

In connection with nurses during the hole treatment period

Background therapy: -

Evidence for comparator: -

| | |
|---|----------------|
| Actual start date of recruitment | 20 August 2013 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

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|--------------------------------------|------------|
| Country: Number of subjects enrolled | Sweden: 12 |
| Worldwide total number of subjects | 12 |
| EEA total number of subjects | 12 |

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) | 6 |
| From 65 to 84 years | 6 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

12 healthy postmenopausal female volunteers, 40 to 70 years old, who were judged to be healthy on the basis of a pre-study physical examination.

Pre-assignment

Screening details:

1. Postmenopausal women with vaginal atrophy
2. Subjects who are willing to participate in the study as indicated by signing the informed consent
3. Subjects who are healthy post-menopausal women between the ages of 40 and 70 years, inclusive

Period 1

| | |
|------------------------------|--------------------------|
| Period 1 title | 25 days (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Blinding implementation details:

It is pharmacokinetic study

Arms

| | |
|------------------|------------------------------------|
| Arm title | Intravaginally use and intravenous |
|------------------|------------------------------------|

Arm description:

Each eligible subject will be administered intravaginally with Vagitocin 400IU [PeP-Tonic Medical AB] once daily for 15 days and a single intravenous dose of oxytocin 10 IU Syntocinon®. There will be a minimum of 7 days washout between the two dosing periods.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Oxytocin 400 IU + Syntocinon |
| Investigational medicinal product code | Oxytocin |
| Other name | |
| Pharmaceutical forms | Gel, Concentrate for suspension for injection |
| Routes of administration | Vaginal use, Intravenous use |

Dosage and administration details:

Each eligible subject will be administered intravaginally with Vagitocin 400IU [PeP-Tonic Medical AB] once daily for 15 days (Period I) and a single intravenous dose of oxytocin 10 IU Syntocinon® (Period II). There will be a minimum of 7 days washout between the two dosing periods.

| | |
|---------------------------------------|------------------------------------|
| Number of subjects in period 1 | Intravaginally use and intravenous |
| Started | 12 |
| Completed | 12 |

Baseline characteristics

End points

End points reporting groups

| | |
|---|------------------------------------|
| Reporting group title | Intravaginally use and intravenous |
| Reporting group description: Each eligible subject will be administered intravaginally with Vagitocin 400IU [PeP-Tonic Medical AB] once daily for 15 days and a single intravenous dose of oxytocin 10 IU Syntocinon®. There will be a minimum of 7 days washout between the two dosing periods. | |

Primary: Oxytocin Plasma

| | |
|--|--------------------------------|
| End point title | Oxytocin Plasma ^[1] |
| End point description: Primary Endpoints - To determine the oxytocin plasma levels after intravaginal and intravenous administration and also pharmacokinetic parameters | |

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|--|---------|
| End point type | Primary |
| End point timeframe: On Day 1, Day 15 (Period I) and Day 22 (Period II) of the study serial blood samples will be collected at the following times relative to dosing: -1.0, -0.5, 0, 0.25, 0.5, 1.0, 1.5, 2.0, 3.0, 4.0, 5.0, 6.0 and 8.0 hours. | |

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: Only following the pmol/L of oxytocin

| | | | | |
|-----------------------------|------------------------------------|--|--|--|
| End point values | Intravaginally use and intravenous | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 12 | | | |
| Units: pmol/L | | | | |
| number (not applicable) | 12 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Recording of Adverse Events (AE/SAE) throughout the study

Adverse event reporting additional description:

Questions at each visit

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

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

| | |
|--------------------|---|
| Dictionary version | 8 |
|--------------------|---|

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: No SAE have been found

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