Clinical trial results:
A pharmacokinetic study of vaginally and intravenously administered oxytocin in postmenopausal women with vaginal atrophy

Summary

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 Pharmcokinetic 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

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

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

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	
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