Clinical trial results:
A phase 2 study investigating the feasibility of using a topical formulation of lidocaine (SHACT) for hysteroscopy in women.

Summary

EudraCT number	2013-001775-20
Trial protocol	SE
Global end of trial date	31 January 2014

Results information

Result version number	v1 (current)
This version publication date	11 January 2022
First version publication date	11 January 2022

Trial information

Trial identification

Sponsor protocol code	PH-HYS-01

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Pharmanest
Sponsor organisation address	Retzius väg 8 Solna, Stockholm, Sweden, SE-171 65
Public contact	Medical Advisor, Pharamanest, +46 70 6083111, gunvor.ekman-ordeberg@ki.se
Scientific contact	Medical Advisor, Pharamanest, +46 70 6083111, gunvor.ekman-ordeberg@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	11 March 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 January 2014
Global end of trial reached?	Yes
Global end of trial date	31 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To obtain initial information regarding the feasibility of using SHACT as a formulation for hysteroscopy .

Protection of trial subjects:

SHACT is administered when the patient is under general anesthesia, according to the Instruction for Use, supplied with the applicator.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 November 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: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	10
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Territory is Sweden.

First patient in: 26-Nov-2013
Last patient out: 15-Jan-2014

Pre-assignment

Screening details:

Inclusion criteria
- Planned for hysteroscopy under anesthesia
- Minimum 18 years of age
- Written informed consent after verbal and written information

Exclusion criteria
- Contraindication for hysteroscopy with lidocaine application at the discretion of the principal investigator
- Known allergy to lidocaine
- Recidivating porphyria

Period 1

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

Arms

Arm title	Overall

Arm description:

Women undergoing hysteroscopy

Arm type	Experimental
Investigational medicinal product name	SHACT 4% viscous solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel, Vaginal solution
Routes of administration	Intracervical use

Dosage and administration details:

SHACT 4% viscous solution consists of a topical preparation which provides analgesia by releasing lidocaine from the vehicle into the mucosa and affecting pain receptors and nerve endings

Number of subjects in period 1	Overall
Started	10
Completed	10

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	10	10	
Age categorical			
The age of the subjects is ≥ 18 yrs			
Units: Subjects			
Adults (18-64 years)	10	10	
Gender categorical			
The subjects were women (≥ 18 yrs) that were planned for hysteroscopy .			
Units: Subjects			
Female	10	10	
Male	0	0	

End points

End points reporting groups

Reporting group title	Overall
Reporting group description:	
Women undergoing hysteroscopy	

Primary: Feasibility of SHACT

End point title	Feasibility of SHACT[1]
End point description:	

End point type	Primary
End point timeframe:	
Feasibility of SHACT was assessed by the principal investigator by responding to a number of questions for each patient after the hysteroscopy was completed.	

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: The primary end point was to obtain initial information regarding the feasibility of using SHACT as a formulation for hysteroscopy.
No statistical analysis was defined in the study protocol.

End point values	Overall			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Patients	10			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

After the patient has wakened up after the hysteroscopy, she is asked about any unusual negative symptoms or signs. The patient is followed up the day after hysteroscopy as well.

Adverse event reporting additional description:

According to the protocol, only adverse events which according to the investigator are unusual and not recognized as expected postoperative symptoms after hysteroscopy were to be recorded as AEs.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	All patients

Reporting group description:

All patients received the study drug and are therefore included in the safety analysis set. Some patients did not receive the full volume of 8.5 ml

Serious adverse events	All patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	All patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 10 (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: There were no serious adverse events in the study. Neither was there any other adverse events reported. According to the protocol, only adverse events which according to the investigator are unusual and not recognized as expected postoperative symptoms after hysteroscopy were to be recorded as AEs.

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