Clinical trial results:
Is there an interest in repeating the vaginal administration of dinoprostone (Propess®) , to promote cervical ripening of pregnant women at term?

Summary

EudraCT number	2016-000147-13
Trial protocol	FR
Global end of trial date	23 April 2022

Results information

Result version number	v1 (current)
This version publication date	08 November 2026
First version publication date	08 November 2026
Summary attachment (see zip file)	Journal article (1-s2.0-S2589933324002362-main.pdf)

Trial information

Trial identification

Sponsor protocol code	I15014

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02888041
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CHU de Limoges
Sponsor organisation address	2 avenue Martin Luther King, Limoges, France, 87042
Public contact	Direction Research and Innovation, CHU de LIMOGES, +33 555056349, drc@chu-limoges.fr
Scientific contact	Direction Research and Innovation, CHU de LIMOGES, +33 555056349, drc@chu-limoges.fr
Sponsor organisation name	CHU de Limoges
Sponsor organisation address	2 avenue martin luther king, limoges, France, 87042
Public contact	Renaud MARTIN, Limoges university hospital, +55 555055555, dri@chu-limoges.fr
Scientific contact	Renaud MARTIN, Limoges university hospital, +33 555055555, dri@chu-limoges.fr

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	20 February 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 April 2022
Global end of trial reached?	Yes
Global end of trial date	23 April 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Demonstrate, if cervical ripening failure by a first Propess®, the laying of a second Propess® (followed if necessary by oxytocin (Syntocinon®)) increases the rate of births vaginally by compared to the direct injection of oxytocin (Syntocinon®).

Protection of trial subjects:

Condition de prise en charge standard pour ce genre de situation

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 July 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 160
Worldwide total number of subjects	160
EEA total number of subjects	160

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)	160
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

recrutement entre décembre 2016 et avril 2022 au niveau national

Pre-assignment

Screening details:

Les patientes sont informées du protocole soit lors de la consultation où le déclenchement est programmé, ou au plus tard, lorsque le déclenchement est débuté (hospitalisation). Les patientes bénéficient donc d'un délai de réflexion de 24 heures minimum.

Period 1

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

Blinding implementation details:

Not applicable

Arms

Are arms mutually exclusive?	Yes
Arm title	Propess

Arm description:

In case of failure of cervical ripening after a first intravaginal delivery device of Dinoprostone (Propess® 10 mg), patients receive a second Propess®, followed by Oxytocin 5U.I/ml (Syntocinon®) (if necessary) and epidural analgesia if desired by the patient.

Arm type	Experimental
Investigational medicinal product name	Dinoprostone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Vaginal delivery system
Routes of administration	Vaginal use

Dosage and administration details:

20 mg milligram(s) total sur une période max de 48H

Arm title	Syntocinon

Arm description:

In case of failure of cervical ripening after a first intravaginal delivery device of Dinoprostone (Propess® 10mg), patients receive directly Oxytocin 5U.I/ml (Syntocinon®) and epidural analgesia if desired by the patient.

Arm type	Active comparator
Investigational medicinal product name	Oxytocin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

10 IU international unit(s) max

Number of subjects in period 1	Propess	Syntocinon
Started	80	80
Completed	80	80

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	160	160	
Age categorical 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)	160	160	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	39.2		
standard deviation	± 1.4	-	
Gender categorical Units: Subjects			
Female	160	160	
Male	0	0	

End points

End points reporting groups

Reporting group title	Propess
Reporting group description:	
In case of failure of cervical ripening after a first intravaginal delivery device of Dinoprostone (Propess® 10 mg), patients receive a second Propess®, followed by Oxytocin 5U.I/ml (Syntocinon®) (if necessary) and epidural analgesia if desired by the patient.	
Reporting group title	Syntocinon
Reporting group description:	
In case of failure of cervical ripening after a first intravaginal delivery device of Dinoprostone (Propess® 10mg), patients receive directly Oxytocin 5U.I/ml (Syntocinon®) and epidural analgesia if desired by the patient.	

Primary: Rate of deliveries vaginally

End point title	Rate of deliveries vaginally
End point description:	
End point type	Primary
End point timeframe:	
At delivery	

End point values	Propess	Syntocinon		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	80		
Units: Pourcentage	19	21		

Statistical analyses

Statistical analysis title	Vaginal delivery rate — between-group comparison
Comparison groups	Propess v Syntocinon
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.715
Method	Chi-squared
Parameter estimate	Relative risk
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.24

Variability estimate	Standard deviation

Secondary: Failure of induction of labor

End point title	Failure of induction of labor

End point description:

End point type	Secondary

End point timeframe:

At delivery

End point values	Propess	Syntocinon		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	80		
Units: Pourcentage	44	15		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the first patient in to last patient out

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Propess
Reporting group description: -	
Reporting group title	Syntocinon

Reporting group description: -

Serious adverse events	Propess	Syntocinon	
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 78 (12.82%)	4 / 79 (5.06%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Pregnancy, puerperium and perinatal conditions			
Retained placenta or membranes			
subjects affected / exposed	1 / 78 (1.28%)	0 / 79 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Third stage postpartum haemorrhage			
subjects affected / exposed	9 / 78 (11.54%)	4 / 79 (5.06%)	
occurrences causally related to treatment / all	2 / 9	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical cord prolapse			
subjects affected / exposed	0 / 78 (0.00%)	1 / 79 (1.27%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Neonatal hypoxia			

subjects affected / exposed	1 / 78 (1.28%)	0 / 79 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neonatal respiratory distress			
subjects affected / exposed	2 / 78 (2.56%)	1 / 79 (1.27%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Propess	Syntocinon	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 78 (19.23%)	15 / 79 (18.99%)	
Pregnancy, puerperium and perinatal conditions			
Retained placenta or membranes			
subjects affected / exposed	6 / 78 (7.69%)	2 / 79 (2.53%)	
occurrences (all)	6	2	
Third stage postpartum haemorrhage			
subjects affected / exposed	9 / 78 (11.54%)	4 / 79 (5.06%)	
occurrences (all)	9	4	
Uterine hypertonus			
subjects affected / exposed	4 / 78 (5.13%)	4 / 79 (5.06%)	
occurrences (all)	4	4	
Uterine tachysystole			
subjects affected / exposed	1 / 78 (1.28%)	5 / 79 (6.33%)	
occurrences (all)	1	5	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 November 2019	Ajout critère de non inclusion

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
24 January 2019	COVID	18 October 2019
23 April 2022	Pas assez d'inclusion	-

Notes:

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/39343101