Clinical trial results:
The Home Induction trial: A randomised open-label trial to assess outpatient induction of labour, and compare efficacy of Propess vs Dilapan-S® for induction of labour at 39 weeks' gestation in normal risk nulliparous women.

Summary

EudraCT number	2019-004697-25
Trial protocol	IE
Global end of trial date	28 July 2023

Results information

Result version number	v1 (current)
This version publication date	10 April 2026
First version publication date	10 April 2026
Summary attachment (see zip file)	HOME IND Results Lancet (HOME IND Results Lancet.pdf)

Trial information

Trial identification

Sponsor protocol code	V609May2023

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Royal College of Surgeons in Ireland
Sponsor organisation address	111 St Stephens Green, Dublin, Ireland,
Public contact	Mandy Jackson, Royal College of Surgeons Ireland, +353 18093863, mandyjackson@rcsi.com
Scientific contact	Mandy Jackson, Royal College of Surgeons Ireland, +353 18093863, mandyjackson@rcsi.com

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	31 July 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 July 2023
Global end of trial reached?	Yes
Global end of trial date	28 July 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate non-inferiority in the efficacy of Dilapan-S® (12 hours or 24 hours insertion) to Propess for outpatient induction of labour at 39 weeks' gestation in otherwise uncomplicated, normal risk* nulliparous women.

the following conditions should be met to consider a pregnancy to be normal risk
Singleton pregnancy
Cephalic presentation
Term gestation (37-39 weeks gestational age)
Maternal pre-pregnancy body mass index < 35kg/m2
Maternal age of ≥ 18 and < 40 years
No evidence of the following conditions:
Pre-pregnancy diabetes
Gestational diabetes
Pre-pregnancy hypertension
Cervical cerclage in situ
Premature rupture of membranes
Congenital fetal anomalies

Protection of trial subjects:

All subjects were consented using a Sponsor approved informed consent SOP and an ethically approved patient information leaflet and consent form.

A Data Safety Monitoring Board was convened to assess the study safety at intervals defined in the charter.

All serious adverse events were captured from Visit 2 until 6 weeks post partum and each SAE that occurred in the trial was reviewed by the Data Safety Monitoring Board

Background therapy:

N/A

Evidence for comparator:

N/A

Actual start date of recruitment	01 July 2020
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	Ireland: 327
Worldwide total number of subjects	327
EEA total number of subjects	327

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)	327
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Identification of potential subjects was from the antenatal clinic lists. Potential participants who wished to enquire about the study through advertising were able to contact the investigator. The expected number of participants available for screening over 30 months was approximately 7500, with a sample size of 327 to be recruited.

Pre-assignment

Screening details:

Participants were identified from the antenatal clinic lists at the maternity site (at <39+0 gestational age). Eligible women who consented to trial participation had their details entered onto the Patient Enrolment Log which identifed the patients by a unique identification number.

Period 1

Period 1 title	Randomisation
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

N/A open label trial

Arms

Are arms mutually exclusive?	Yes
Arm title	Propess

Arm description:

Patients randomised to receive Propess administered vaginally at a standard dosing protocol, i.e. 1 device containing 10mg dinoprostone over 24 hours

Arm type	Experimental
Investigational medicinal product name	Propess (Cervidil)
Investigational medicinal product code	
Other name	Dinoprostone 10mg vaginal insert
Pharmaceutical forms	Vaginal delivery system
Routes of administration	Vaginal use

Dosage and administration details:

10mg vaginal delivery system over 24 hours

Arm title	Dilapan 12

Arm description:

Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 12 hours

Arm type	Experimental
Investigational medicinal product name	Dilapan-S
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Vaginal delivery system
Routes of administration	Intracervical use

Dosage and administration details:

Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 12 hours

Arm title	Dilapan 24

Arm description:

Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 24 hours.

Arm type	Experimental
Investigational medicinal product name	Dilapan-S
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Vaginal delivery system
Routes of administration	Intracervical use

Dosage and administration details:

Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 24 hours

Number of subjects in period 1	Propess	Dilapan 12	Dilapan 24
Started	110	107	110
Completed	87	88	96
Not completed	23	19	14
Consent withdrawn by subject	5	2	5
unknown	-	2	-
spontaneous onset of labour	12	12	7
developed exclusion criteria	6	3	2

Period 2

Period 2 title	Post Randomisation Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

N/A

Arms

Are arms mutually exclusive?	Yes
Arm title	Propess

Arm description:

Patients randomised to receive Propess administered vaginally at a standard dosing protocol, i.e. 1 device containing 10mg dinoprostone over 24 hours.

Arm type	Experimental
Investigational medicinal product name	Propess (Cervidil)
Investigational medicinal product code	
Other name	Dinoprostone 10mg vaginal insert
Pharmaceutical forms	Vaginal delivery system
Routes of administration	Vaginal use

Dosage and administration details:

10mg vaginal delivery system over 24 hours

Arm title	Dilapan 12

Arm description:

Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 12 hours

Arm type	Experimental
Investigational medicinal product name	Dilapan-S
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Vaginal delivery system
Routes of administration	Intracervical use

Dosage and administration details:

Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 12 hours

Arm title	Dilapan 24

Arm description:

Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 24 hours.

Arm type	Experimental
Investigational medicinal product name	Dilapan-S
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Vaginal delivery system
Routes of administration	Intracervical use

Dosage and administration details:

Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 24 hours

Number of subjects in period 2	Propess	Dilapan 12	Dilapan 24
Started	87	88	96
Completed	87	88	96

Baseline characteristics

Reporting groups	
Reporting group title	Propess
Reporting group description:	
Patients randomised to receive Propess administered vaginally at a standard dosing protocol, i.e. 1 device containing 10mg dinoprostone over 24 hours	
Reporting group title	Dilapan 12
Reporting group description:	
Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 12 hours	
Reporting group title	Dilapan 24
Reporting group description:	
Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 24 hours.	

Reporting group values	Propess	Dilapan 12	Dilapan 24
Number of subjects	110	107	110
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	27.3	27.4	27.1
standard deviation	± 4.8	± 5.3	± 5.2
Gender categorical Units: Subjects			
Female	110	107	110
Male	0	0	0
Body Mass Index Units: kilogram(s)/square metre			
arithmetic mean			
standard deviation	±	±	±

Reporting group values	Total		
Number of subjects	327		
Age categorical Units: Subjects			
In utero	0		

Preterm newborn infants (gestational age < 37 wks)	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)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	327		
Male	0		
Body Mass Index			
Units: kilogram(s)/square metre			
arithmetic mean			
standard deviation	-		

Subject analysis sets

Subject analysis set title	Per protocol analysis
Subject analysis set type	Per protocol

Subject analysis set description:

The primary analysis population for non-inferiority will be the per-protocol population. The analyses performed was in the per-protocol population, supported by an intention-to-treat analysis.

Reporting group values	Per protocol analysis		
Number of subjects	271		
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: years			
arithmetic mean	27.2		
standard deviation	± 5.1		
Gender categorical			
Units: Subjects			
Female	271		

Male	0		

Body Mass Index Units: kilogram(s)/square metre			
arithmetic mean	25.7		
standard deviation	± 4		

End points

End points reporting groups

Reporting group title	Propess
Reporting group description:	
Patients randomised to receive Propess administered vaginally at a standard dosing protocol, i.e. 1 device containing 10mg dinoprostone over 24 hours	
Reporting group title	Dilapan 12
Reporting group description:	
Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 12 hours	
Reporting group title	Dilapan 24
Reporting group description:	
Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 24 hours.	

Reporting group title	Propess
Reporting group description:	
Patients randomised to receive Propess administered vaginally at a standard dosing protocol, i.e. 1 device containing 10mg dinoprostone over 24 hours.	
Reporting group title	Dilapan 12
Reporting group description:	
Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 12 hours	
Reporting group title	Dilapan 24
Reporting group description:	
Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 24 hours.	
Subject analysis set title	Per protocol analysis
Subject analysis set type	Per protocol
Subject analysis set description:	
The primary analysis population for non-inferiority will be the per-protocol population. The analyses performed was in the per-protocol population, supported by an intention-to-treat analysis.	

Primary: Vaginal Delivery Rate

End point title	Vaginal Delivery Rate
End point description:	

End point type	Primary
End point timeframe:	
Measured at Visit 4 (delivery visit)	

End point values	Propess	Dilapan 12	Dilapan 24	Per protocol analysis
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	87	88	96	271
Units: vaginal deliveries	16	28	48	194

Statistical analyses

Statistical analysis title	Statistical analysis primary endpoint

Statistical analysis description:

Median [inter-quartile range] or mean (standard deviation), in the absence of skewness, were used to summarize outcome data. SAS Version 9.2 was used to analyse the data

Comparison groups	Propess v Dilapan 12 v Dilapan 24 v Per protocol analysis
Number of subjects included in analysis	542
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
P-value	= 0.026 [2]
Method	Wald Test

Notes:

[1] - A non-inferiority margin of 10% in vaginal delivery rates was considered to be clinically meaningful, consistent with other trials comparing induction methods in the inpatient setting. Given that this was a non-inferiority trial, the per-protocol analysis was considered the primary population for analysis, although an ITT analysis was also completed. Median [inter-quartile range] or mean (standard deviation), in the absence of skewness, were used to summarize outcome data. SAS Version 9.2 used

[2] - A non-inferiority p-value, using a Wald test, was calculated to aid interpretation

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All Adverse Events (AEs) occurring during the trial were recorded on the CRF, except for those events that met the definition of a non-reportable event. All AEs were recorded from Visit 2 until 6 weeks post partum.

Adverse event reporting additional description:

There were overall 20 SAEs that occurred in this trial and within certain SAEs, there were multiple events to be MedDRA coded within a case. Therefore the below represents a total of 20 SAE cases only.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26

Reporting groups

Reporting group title	Propess

Reporting group description:

Patients randomised to receive Propess administered vaginally at a standard dosing protocol, i.e. 1 device containing 10mg dinoprostone over 24 hours.

Reporting group title	Dilapan 12

Reporting group description:

Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 12 hours

Reporting group title	Dilapan 24

Reporting group description:

Patients randomised to receive Dilapan-S® at a standard dosing protocol, i.e. the required number of rods intra-cervically over 24 hours.

Serious adverse events	Propess	Dilapan 12	Dilapan 24
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 88 (6.82%)	5 / 87 (5.75%)	9 / 96 (9.38%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Subgaleal haematoma			
subjects affected / exposed	0 / 88 (0.00%)	1 / 87 (1.15%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subgaleal haemorrhage			

subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Cooling therapy			
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis prophylaxis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Postpartum haemorrhage			
subjects affected / exposed	1 / 88 (1.14%)	1 / 87 (1.15%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 88 (1.14%)	2 / 87 (2.30%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Vulvovaginal burning sensation			
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Neonatal respiratory distress			
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient tachypnoea of the newborn			

subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Coagulation test abnormal			
subjects affected / exposed	0 / 88 (0.00%)	1 / 87 (1.15%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ultrasound head abnormal			
subjects affected / exposed	0 / 88 (0.00%)	1 / 87 (1.15%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood gases abnormal			
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood lactic acid increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	1 / 88 (1.14%)	1 / 87 (1.15%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Injury to brachial plexus due to birth trauma			
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iatrogenic injury			
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Perineal injury			
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Congenital pneumonia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Phrenic nerve paralysis			
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 88 (0.00%)	1 / 87 (1.15%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice neonatal			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Lower respiratory tract infection			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inclusion conjunctivitis neonatal			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 88 (0.00%)	1 / 87 (1.15%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection			
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastitis			
subjects affected / exposed	2 / 88 (2.27%)	0 / 87 (0.00%)	2 / 96 (2.08%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 88 (0.00%)	1 / 87 (1.15%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdiaphragmatic abscess			
subjects affected / exposed	0 / 88 (0.00%)	1 / 87 (1.15%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 88 (0.00%)	1 / 87 (1.15%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding disorder			
subjects affected / exposed	0 / 88 (0.00%)	1 / 87 (1.15%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Propess	Dilapan 12	Dilapan 24
Total subjects affected by non-serious adverse events			
subjects affected / exposed	54 / 88 (61.36%)	51 / 87 (58.62%)	53 / 96 (55.21%)
Investigations			
Neutrophilia	Additional description: Raised WCC or Neutrophilia		
subjects affected / exposed	3 / 88 (3.41%)	3 / 87 (3.45%)	3 / 96 (3.13%)
occurrences (all)	3	3	3
Surgical and medical procedures			
Retained placenta operation			
subjects affected / exposed	1 / 88 (1.14%)	1 / 87 (1.15%)	0 / 96 (0.00%)
occurrences (all)	1	1	0
Cardiac disorders			
Bradycardia	Additional description: Maternal bradycardia		
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	1 / 96 (1.04%)
occurrences (all)	1	0	1
Tachycardia	Additional description: Maternal tachycardia >100bpm		
subjects affected / exposed	11 / 88 (12.50%)	7 / 87 (8.05%)	13 / 96 (13.54%)
occurrences (all)	11	7	13
Nonreassuring foetal heart rate pattern	Additional description: Non reassuring fetal testing		
subjects affected / exposed	30 / 88 (34.09%)	32 / 87 (36.78%)	29 / 96 (30.21%)
occurrences (all)	30	32	29
Nervous system disorders			
Headache	Additional description: Post dural headache		
subjects affected / exposed	2 / 88 (2.27%)	1 / 87 (1.15%)	1 / 96 (1.04%)
occurrences (all)	2	1	1
Pregnancy, puerperium and perinatal conditions			
Shoulder dystocia			
subjects affected / exposed	0 / 88 (0.00%)	1 / 87 (1.15%)	1 / 96 (1.04%)
occurrences (all)	0	1	1
Uterine hyperstimulation			
subjects affected / exposed	3 / 88 (3.41%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences (all)	3	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia <80g/L		
subjects affected / exposed	1 / 88 (1.14%)	2 / 87 (2.30%)	1 / 96 (1.04%)
occurrences (all)	1	2	1
Thrombocytopenia			

subjects affected / exposed	0 / 88 (0.00%)	1 / 87 (1.15%)	2 / 96 (2.08%)
occurrences (all)	0	1	2
Respiratory, thoracic and mediastinal disorders			
Tachypnoea			
subjects affected / exposed	1 / 88 (1.14%)	2 / 87 (2.30%)	0 / 96 (0.00%)
occurrences (all)	1	2	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 88 (0.00%)	1 / 87 (1.15%)	0 / 96 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 88 (1.14%)	0 / 87 (0.00%)	0 / 96 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 88 (0.00%)	0 / 87 (0.00%)	2 / 96 (2.08%)
occurrences (all)	0	0	2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 January 2021	Version 2 protocol dated 11-Jan-2021: details of amendment: "Removal of the following non-reportable Aes from protocol: 1. Failure to progress in labour 2. Non-reassuring fetal heart rate tracings during labour 3. Obstetric need for cesarean delivery, forceps-assisted delivery, vacuum-assisted delivery, or episiotomy "
19 February 2021	Clarity added around timeframe in exclusion criterion Addition of non-reportable concomitant medications Footnote added to schedule of assessments to allow partner of trial subjects to receive phonecalls
01 October 2021	Version 4 protocol dated 01-Oct-2021 had the following changes: "Additional site and contact details added Recruitment numbers updated to reflect second site Visit 5 amended to allow for phone or chart review follow up Visit 3 timeframe amended Footnotes added to schedule of assessments for clarity on procedures Addition of non reportable AE of ""infections unrelated to labour and delivery"""

28 November 2022	Version 5 protocol amended: -Removal of National Maternity Hospital as a site and corresponding National Maternity Hospital PI details -Changed from 24 to 30 months -Clarity provided in the inclusion criteria around what are considered relevant medical issues that would be considered when assessing eligibility. Wording added also to outline that this is assessed on a case by case basis. -Clarity provided in the exclusion criteria that known maternal health problems that would directly affect the risk status of the woman are exclusionary. Wording added also to outline that this is assessed on a case by case basis. -updated risks section; Updated based on revisions to Section 4.8 of the Propess SmPC. Based on new Propess SmPC dated 17-Nov-2021 and Typo corrected "tocolytics" -Statistical changes made by statistician -Wording amended to allow for scenario where Propess or Dilapan falls out -section added regarding new born admissions that are to be captured as adverse events. Non reportable adverse events for the new born were added. -events were added to the non-reportable adverse events in pregnancy
09 May 2023	Protocol V6 amended with wording regarding number of subjects planned revised to read "recruitment will continue until 285 subjects can be analysed"

Notes:

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/36814336