ISRCTN11067866 https://doi.org/10.1186/ISRCTN11067866

A prospective comparative trial of Dilapan-S compared with Propess for induction of labor at 41+ weeks in nulliparous pregnancy

Submission date
12/07/2017

Recruitment status
No longer recruiting

Registration date
14/07/2017

Overall study status
Completed

Last Edited
14/07/2017

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
An induced labour is one that is started artificially, for example when the baby is overdue. Induction of labour when the cervix (neck of the womb) is not adequately prepared can lead to a longer labour compared to when labour commences naturally. To increase the success of labour induction, it is essential that the cervix is ready or "favourable". The methods of induction of labour are generally divided into two categories: using hormones (vaginal medication containing hormones) which can prepare the cervix before labour, and using a dilation device (cervix dilator with no hormones) which stimulates the body's natural hormones to prepare the cervix before labour. Dilation methods have been shown to work as well as hormonal methods. Dilation methods have also been shown to have improved outcomes for mother and baby when compared to hormonal methods. The aim of this study is to find out whether the mechanical cervical dilator Dilapan-S is an acceptable, safe way to induce labour.

Who can participate?
Women in their first pregnancy with no complications who are scheduled for induction of labour

What does the study involve?
Eligible patients fulfilling the study criteria on weekdays (Monday to Friday inclusive) are approached for study participation and offered induction with Dilapan-S or routine induction of labour with Propess. Those who opt for routine care and eligible women receiving Propess at weekends are used as the control group. Women who have a closed cervix and are therefore unable to have Dilapan-S instead receive Propess. Dilapan-S or Propess are inserted into the cervix and left in place for up to 24 hours before reassessment, unless removal is clinically indicated before this time. If the cervix is still unfavorable at reassessment, up to two prostin gels are used. Labour outcomes are recorded and compared between the two treatments.

What are the possible benefits and risks of participating?
Dilapan-S is a proven, safe mechanical cervical dilator. Dilation methods have also been shown to have improved outcomes for mother and baby when compared to hormonal methods in previous studies.

Where is the study run from?
National Maternity Hospital (Ireland)

When is the study starting and how long is it expected to run for?
May 2017 to November 2017

Who is funding the study?
OLM Ltd (provided Dilapan-S free of charge)

Who is the main contact?
Dr David Crosby

Contact information

Type(s)
Scientific

Contact name
Dr David Crosby

Contact details
National Maternity Hospital
Holles Street
Dublin
Ireland
D2

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2017-002969-22

Study information

Scientific Title
A prospective comparative trial of Dilapan-S compared with Propess for induction of labor at 41+ weeks in nulliparous pregnancy

Study objectives
To determine whether mechanical induction with Dilapan-S is an acceptable, safe method of induction of labor in post-dates uncomplicated nulliparous pregnancy.

Ethics approval required

Old ethics approval format

Ethics approval(s)
National Maternity Hospital Dublin Ethics Committee, May 2017

Study design
Preliminary prospective comparative pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Obstetrics: induction of labor

Interventions
Eligible patients fulfilling study criteria on weekdays (Monday to Friday inclusive) were approached for study participation. Study participation was induction with Dilapan-S versus routine induction of labor with Propess. Between Monday and Fridays, n=26 of eligible women approached agreed to Dilapan-S and n=22 number opted for routine care. Those who opted for routine care and eligible women receiving Propess at weekends (n=4) were used as the control group. Administration of Dilapan-S or Propess was by the clinician assigned to the antenatal ward on the day of study. If women had a closed cervix and therefore unable to have Dilapan-S, Propess was administered. Analysis was by intention-to-treat.

Dilapan-S
Between 1 and 5 Dilapan-S rods were inserted into the cervix by the clinician depending on the Bishop's Score of the cervix as per manufacturer's instructions. Dilapan-S rods were left in situ for up to 24 hours prior to reassessment, unless removal was clinically indicated prior to this time. If the cervix was still unfavorable at reassessment, up to two prostin (Intracervical PGE2) gels were used.

Propess (Dinoprostone 10mg)
Propess was inserted into the posterior fornix of the cervix as per manufacturer's instructions. Propess pessary was left in situ for up to 24 hours prior to reassessment as per hospital policy, unless removal was clinically indicated prior to this time. If the cervix was still unfavorable at reassessment, up to two prostin (Intracervical PGE2) gels were used.

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dinoprostone

Primary outcome measure
1. Compliance with study protocol, quantified as the proportion of women who agreed to study participation and who completed the trial protocol of insertion of Dilapan-S. This occurred at time of insertion of the product
2. Safety: Maternal infection defined as maternal temperature greater than 38ºC, endometritis, chorioamnionitis or antibiotic usage following study allocation until delivery of baby
3. Safety: Maternal hyperstimulation defined as > 7 contractions in 15 minutes at any time following study allocation until delivery of baby
4. Safety: Neonatal infection defined as fever, suspected or proven sepsis, or need for antibiotic use in the first 72 hours of life
5. Safety: Neonatal Apgar scores at 1 and 5 minutes of life

Secondary outcome measures
1. Change in Bishop's score pre and post-induction (within 24 hours of insertion of induction agent)
2. Complications associated with induction agent (within 24 hours of insertion of induction agent):
2.1. Cervical injury
2.2. Bleeding during insertion or removal
2.3. Spontaneous expulsion
2.4. Retraction into cavity
2.5. Dilator entrapment
2.6. Dilator fragmentation
2.7. Rupture of membranes
2.8. Other
3. Median duration from induction to delivery in minutes
4. Median duration of induction agent in situ in minutes
5. Delivery within 24 hours of receiving induction of labor method
6. Cesarean delivery rate
7. Instrumental delivery rate
8. Additional use of prostaglandin (1 or 2 doses) after reassessment following removal of initial product (Dilapan-S or Dinoprostone)
9. Additional use of oxytocin for labour induction or augmentation
10. Epidural use in labor
11. 3rd and 4th degree tears
12. Manual removal of placenta
13. Postpartum hemorrhage > 1L and post-partum blood transfusion (within 72 hours of delivery)
14. Meconium at delivery
15. Neonatal intensive care unit (NICU) admission (within 72 hours of delivery)

Overall study start date
22/05/2016

Completion date
30/11/2016

Eligibility

Key inclusion criteria
1. Pregnant women in their first pregnancy (nulliparous women)
2. Adequate English to understand the purpose of the study
3. Scheduled for induction of labor for post-dates (≥41 weeks gestation)
4. Unfavorable cervix defined as Bishops Score ≤6
5. Not suitable for artificial rupture of membranes (ARM)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
50

Key exclusion criteria
1. Any pre-existing medical condition or medical condition of pregnancy
2. Pathological CTG prior to induction
3. Oligohydramnios on post-dates scan
4. 2 or more LLETZ treatments
5. Maternal age <18 years old or >40 years old
6. Body mass index ≥30kg/m2
7. Women with a closed cervix, insertion was not possible and so were unable to receive Dilapan-S

Date of first enrolment
22/05/2016

Date of final enrolment
23/11/2016

Locations

Countries of recruitment
Ireland

Study participating centre
National Maternity Hospital
Holles Street

Dublin 2
Ireland
D2

Sponsor information

Organisation
National Maternity Hospital

Sponsor details
Holles Street
Dublin 2
Ireland
D2

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type
Industry

Funder Name
OLM Ltd (provided Dilapan-S free of charge)

Results and Publications

Publication and dissemination plan
Submitted to a high impact peer reviewed journal with intent to publish the findings in the next year.

Intention to publish date
13/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to data protection issues.

IPD sharing plan summary

Not expected to be made available