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Labor Induction with Foley catheter and E1-prostaglandin analogs in Poland (LIFE-PL Study)

Submission date
03/01/2024

Recruitment status
No longer recruiting

Registration date
05/01/2024

Overall study status
Completed

Last Edited
21/08/2024

Condition category
Respiratory

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

Plain English Summary
Background and study aims
Induction of labor can be defined as artificial release of the uterine contractions before its spontaneous commencement. Currently, up to every third pregnant woman undergoes this procedure, and in the group of vaginal births this percentage reaches almost 40%. The rationale behind the use of labor induction is to reduce perinatal fetal and neonatal morbidity and mortality, as well as to minimize maternal complications for specific indications.
The most important element determining the effectiveness of labor induction is the condition of the cervix and its maturity. If the cervix is unfavorable, pre-induction of labor should be performed. If the cervix is unfavorable when starting IOL then ripening of the cervix can increase the success of IOL and shorten labor duration. Cervical ripening can be done either pharmacologically with prostaglandins analogues (i.e oral Misoprostol) or mechanically with a single balloon (Foley) catheter. Both methods of cervical ripening are safe and highly effective without increasing the risk of birth complications. If contractions do not develop after the use of oral Misoprostol / Foley catheter within 24 hours, patients will receive an intravenous infusion of oxytocin to induce uterine contractions.
This study will compare the efficacy and safety profile of the two different induction of labor regimens in patients with indications of labor induction - single ballon Foley catheter vs. oral Misoprostol.

The primary outcome is to evaluate the time from labor induction regimen administration to delivery (both vaginal and cesarean) within 24–48 h. The secondary outcomes will be the proportion of women undergoing cesarean section or operative delivery, oxytocin augmentation, and the necessity for intrapartum analgesia application. In addition, we compared the groups regarding the percentage of vaginal births and the rate of cesarean sections. Finally, we also compared the groups regarding the occurrence of uterine hyperstimulation (tachysystole).

Who can participate?
Women aged 18 years or over, in their first or subsequent singleton pregnancy, with labor induction indications (in accordance with current recommendations of the Polish Society of Gynecologists and Obstetricians) and who have an unfavorable cervix (Bishop score <6) with fetus is in the cephalic position.

What does the study involve?
Participation in this study is completely voluntary. Eligible women admitted to the department of Obstetrics and Gynecology, after meeting inclusion criteria will be given opportunity to participate in the study. If, after receiving a preliminary information about the study, they are interested in participation, they will be given further information and asked for signed consent. Subsequently, patients will be allocated to one of the two induction of labor regimens: either using a Foley balloon catheter or Misoprostol taken orally. Patients will be randomized in 1 to 1 manner. It means that patients will receive the selected method of labor induction alternately. The first patient will receive a Foley catheter. The next one will receive oral Misoprostol and so on.

What are the possible benefits and risks of participating?
Since both induction of labor regimens are well established in clinical practice, this trial should bring no disadvantage or risk to the patients.
Referring to current guidelines, women with indications for labor induction should undergo this procedure to minimize both maternal and neonatal complications.
The difference with the standard regimen of labor induction outside the study is that the method of cervical ripening used will be determined in accordance with the applicable randomization and not according to the patients' preferences. In addition, patient care will not differ from the standards applicable in our department.

Where is the study run from?
1. Department of Obstetrics and Gynecology, St. Adalbert’s Hospital in Gdańsk, Copernicus Healthcare Entity, 80-462 Gdańsk, Poland
2. 2nd Department of Gynecology and Obstetrics, Wroclaw Medical University, 50-552 Wroclaw, Poland

When is the study starting and how long is it expected to run for?
November 2023 to August 2024

Who is funding the study?
Department of Obstetrics and Gynecology, St. Adalbert’s Hospital in Gdańsk, Copernicus Healthcare Entity, 80-462 Gdańsk, Poland

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KB 46/23

Study information

Scientific Title
A prospective randomized controlled trial (RCT) evaluating the effectiveness of a pharmacological pre-induction and induction of labor protocol using an oral prostaglandin E1

analogue and oxytocin compared to a protocol of mechanical pre-induction and induction of labor using a single-balloon Foley catheter, in and oxytocin in patients scheduled for induction of labor.

Acronym
LIFE-PL

Study hypothesis
1. Pharmacological pre-induction and induction of labor regimen using an oral prostaglandin E1 is equally safe with a regimen of mechanical pre-induction and induction of labor using a single-balloon Foley catheter.
2. Pharmacological pre-induction and induction of labor regimen using an oral prostaglandin E1 is equally effective with regimen of mechanical pre-induction and induction of labor using a single-balloon Foley catheter in achieving vaginal delivery within 48 hours

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/11/2023, Bioethical Commission of Okręgowa Izba Lekarska in Gdańsk (Śniadeckich 33, Gdańsk, 80-204, Poland; +48 (58) 524 32 50; kb@gdansk.oil.org.pl), ref: KB - 46 / 23

Study design
Multicenter randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Efficacy

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

Condition
Comparison of the effectiveness and safety of two pre-induction and labor induction regimens

Interventions
The study will include an assessment and comparison of the effectiveness of two popular methods of labor pre-induction: Foley catheter (mechanical method) and oral E1-prostaglandin analogues (pharmacological method).
Depending on the agent used, labor induction will be carried out according to the following regimen: 200 micrograms of Misoprostol consumed orally (divided into 4 doses of 50 micrograms each) or single-balloon catheter in the form of Foley catheter insertion above the

internal ostium of the cervical canal. Once the Foley catheter had passed through the cervical canal, the catheter balloon was filled with sterile saline to a volume of 80–100 mL.
If contractions did not develop after the use of a Foley catheter/oral Misoprostol within 24 hours, the patient received an intravenous infusion of oxytocin to induce labor.
Randomization will be performed based on a single sequence of random assignments. Patients will be randomly assigned to a given research group in a 1:1 ratio.

Intervention Type
Procedure/Surgery

Primary outcome measure
Time from labor induction regimen administration to delivery (both vaginal and cesarean) within 24–48 h measured using patient records

Secondary outcome measures
Measured using patient records at the end of the study:
1. Proportion of women undergoing cesarean section or operative delivery
2. Oxytocin augmentation
3. Necessity for intrapartum analgesia application
4. Number of vaginal births and of cesarean sections
5. Clinical condition of patients and newborns
6. Occurrence of uterine hyperstimulation (tachysystole)

Overall study start date
15/10/2023

Overall study end date
18/08/2024

Eligibility

Participant inclusion criteria
1. Single live pregnancy
2. Cephalic fetal presentation
3. No history of previous uterine operations (i.e. cesarean section)
4. Indications for induction of labor in accordance with current recommendations of the Polish Society of Gynecologists and Obstetricians
5. Lack of contraindications to vaginal delivery
6. Confirmed well-being of the mother and fetus
7. Informed consent to participate in the study
8. Unfavourable cervix
9. Full-term pregnancy (>37 weeks of pregnancy)

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Female

Target number of participants
300

Participant exclusion criteria
1. Presence of uterine scar
2. Onset of spontaneous labor
3. Premature rupture of membranes (PROM)
4. Non-cephalic fetal position
5. Multiple pregnancy
6. Suspected intrauterine infection
7. Contraindications to vaginal delivery and induction of labor following the Polish guidelines

Recruitment start date
23/11/2023

Recruitment end date
31/03/2024

Locations

Countries of recruitment
Poland

Study participating centre
Department of Obstetrics and Gynecology, St. Adalbert's Hospital in Gdańsk, Copernicus Healthcare Entity
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Study participating centre
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Sponsor information

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Sponsor type
University/education

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-reviewed journal

Intention to publish date
10/10/2024

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study are not expected to be made available due to to the risk of the possibility of deanonymization.

IPD sharing plan summary
Not expected to be made available