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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
25/03/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

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 oral Misoprostol. The next one will receive a Foley catheter 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?
Department of Obstetrics and Gynecology, St. Adalbert’s Hospital in Gdańsk, Copernicus Healthcare Entity, 80-462 Gdańsk, Poland

When is the study starting and how long is it expected to run for?
November 2023 to October 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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Additional identifiers

Protocol serial number
KB 46/23

Study information

Scientific Title
A prospective quasi-randomized controlled trial 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, and oxytocin in patients scheduled for induction of labor

Acronym
LIFE-PL

Study objectives
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

Primary study design
Interventional

Study design
Single-center quasi-randomized controlled trial

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
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(s)
Time from labor induction regimen administration to delivery (both vaginal and cesarean) within 24–48 h measured using patient records

Key secondary outcome(s)
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)

Completion date
10/10/2024

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Female

Total final enrolment
665

Key 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

Date of first enrolment
23/11/2023

Date of final enrolment
10/10/2024

Locations

Countries of recruitment
Poland

Study participating centre
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Sponsor information

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Department of Perinatology, Gynecology and Gynecologic Oncology, Faculty of Health Sciences, Collegium Medicum in Bydgoszcz, Nicolaus Copernicus University

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available