ISRCTN26164110 https://doi.org/10.1186/ISRCTN26164110

A comparison of outpatient with inpatient mifepristone usage for cervical ripening before labor induction

Submission date
17/12/2019

Recruitment status
No longer recruiting

Registration date
21/02/2020

Overall study status
Completed

Last Edited
22/05/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
In recent years, labor induction has become more frequent, currently accounting for about 20% of pregnancies. Main indications are: prolonged pregnancy, premature rupture of membranes, high blood pressure (hypertension and preeclampsia), diabetes. Several methods have been described to promote both cervical maturation and labor itself.
The drug Mifepristone has been shown to increase uterine activity and cervical maturation. Firstly, it was used for medically induced abortion, then studies have emerged on possibilities of mifepristone usage for cervical ripening before labor induction at term pregnancy.

Who can participate?
Pregnant women aged 18 – 45 years, at 39 – 41 weeks gestation.

What does the study involve?
Participants will be given a dose of mifepristone and monitored closely if labor is not started after 24 hours, she will be given a second dose of the drug and monitored again.

What are the possible benefits and risks of participating?
Possibly, there will be not any difference in the maternal and perinatal outcomes between outpatient and inpatient groups, but perhaps women will prefer to be at home at the time of cervical ripening. Secondly, outpatient management is favorable by economic reasons.

Where is the study run from?
National Medical Research Center for Obstetrics, Gynecology and Perinatology (V.I.Kulakov), Russia

When is the study starting and how long is it expected to run for?
January 2020 to October 2021

Who is funding the study?
National Medical Research Center for Obstetrics, Gynecology and Perinatology named after Academician V.I.Kulakov of the Ministry of Healthcare of the Russian Federation

Who is the main contact?
1. Prof. Oleg Baev (scientific)
metod_obsgyn@hotmail.com
2. Anna Karapetian (public)
anne-89@mail.ru

Contact information

Type(s)
Scientific

Contact name
Prof Oleg Baev

ORCID ID
https://orcid.org/0000-0001-8572-1971

Contact details
Academika Oparina St.,4
Moscow
Russian Federation
117997
+7 (916) 389 75 22
metod_obsgyn@hotmail.com

Type(s)
Public

Contact name
Mrs Anna Karapetian

ORCID ID
https://orcid.org/0000-0001-8555-144X

Contact details
Academika Oparina St.,4
Moscow
Russian Federation
117997
+7 (495) 438-11-66
inter_otdel@mail.ru

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
№ 4, 12/04/2018

Study information

Scientific Title
A comparison of outpatient with inpatient mifepristone usage for cervical ripening: a randomized control study

Study objectives
Is outpatient mifepristone usage efficient in cervical ripening for labor induction? Is outpatient usage of mifepristone for cervical ripening as safe as inpatient? Is outpatient usage of mifepristone for cervical ripening more favorable than inpatient in term of economic benefit?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2018, Ethics commission of Federal State Budget Institution (National medical research center for obstetrics, gynecology and perinatology named after academician V.I. Kulakov of the Ministry of Healthcare of Russian Federation, Akademika Oparina St., 4, 117997, Moscow, Russia; +7 (495) 438 25 00, n_dolgushina@oparina4.ru), ref: n/a

Study design
Interventional single-centre trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Pre-induction of labour

Interventions
The study of efficiency and safety of outpatient mifepristone usage for cervical ripening will be conducted in a large tertiary center in Moscow between January 2020 and June 2021. Primiparous and multiparous women with a singleton pregnancy with fetus in cephalic presentation at gestational age between 39 and 41+6 weeks, cervical Bishop’s score 6 or less and indications for labor induction (of which the induction can be postponed for 24-48 h) will be invited to participate in the trial. Gestational age will be confirmed by the first-trimester ultrasound.

Participants will be randomly assigned to either Group Outpatient or Group Inpatient (control) based on computer-generated random numbers. Principle of block randomization will be used to assign patients to the groups, with a block size of ten. An envelope should be opened for all

consecutive participants to reveal their group assignment at the moment when they recruit into the study.

Patients of Group Outpatient will discharge after mifepristone administration. A written document with all the information that should bring them back to the hospital (information for patient) will be given. Patients in Group Inpatient will receive mifepristone and stay in the inpatient setting in accordance to the Department's protocol.

Detailed methodology:
Women will be considered for recruitment into the study after collection anamnesis data, pelvic examination for assessment Bishop's score and signed informed consent. Before drug taking, fetal wellbeing will be evaluated using cardiotocography (CTG). If fetal heart normal, the drug will be given and woman will be sent home. The woman will be advised to come to the maternity unit if she has uterine contractions, abdominal pain, bleeding, preterm rupture of membranes or reduced fetal movements. If she will not have any of the above mentioned symptoms, she will be asked to come after 24 hours from the first drug taking to assess fetal wellbeing and cervical reassessment. In case of 8 points and more on Bishop's scale, women will be hospitalized to the maternity unit for further labor induction: amniotomy and, if uterine contractions are absent within 4 hours, oxytocin infusion. If the Bishop's score is less than 8 and fetal condition is normal, the woman will receive the second tablet of mifepristone and be sent home for next 24 hours with the same recommendations. After 24 hours participant will admit to the maternity unit. Further induction plan will be determined depending on Bishop's score, according to local induction protocol. If Bishop's score is 7 and less – osmotic dilators and/or intracervical prostaglandin E2 gel (maximum three times with 6 hours intervals). If Bishop's score is 8 and more – amniotomy and, if uterine contractions are absent within 4 hours, oxytocin infusion. Before and after interventions fetal condition will be checked. For inpatient women the pre-induction plan by mifepristone and further management are similar to outpatient.

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome(s)
1. Bishop's score after 24 and 48 h of the mifepristone administration
2. Additional use of prostaglandin E2 and/or mechanical methods for cervical ripening
3. Additional use of oxytocin
4. Operative delivery rate
5. Interval from cervical ripening start and labour onset

Key secondary outcome(s))
1. Induction to delivery interval (IDI, from first mifepristone intake to delivery)
2. Rate of adverse effects
3. Perinatal outcomes

Completion date
14/10/2021

Eligibility

Key inclusion criteria
1. Age 18-45 years
2. Gestational age of 39 - 41 weeks
3. Singleton gestation
4. Cephalic presentation
5. Bishop score 6 or less
6. Indications for labor induction (of which the induction can be postponed for 24-48 h)
7. Normal CTG tracing

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Total final enrolment
322

Key exclusion criteria
1. Transverse lie or presentation other than cephalic
2. Ultrasonographic estimated fetal weight greater than 4500 g or other evidence of cephalopelvic disproportion
3. Placenta previa or other unexplained vaginal bleeding
4. Previous cesarean or history of uterine surgery
5. Severe preeclampsia
6. Evidence of chorioamnionitis
7. Severe form of any preexisting medical disease

Date of first enrolment
21/02/2020

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
Russian Federation

Study participating centre
National Medical Research Center for Obstetrics, Gynecology and Perinatology (V.I.Kulakov)
Academician Oparina St.,4
Moscow
Russian Federation
117198

Sponsor information

Organisation
National Medical Research Center for Obstetrics, Gynecology and Perinatology named after Academician V.I.Kulakov of the Ministry of Healthcare of the Russian Federation

ROR
https://ror.org/03yfnyw34

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Medical Research Center for Obstetrics, Gynecology and Perinatology named after Academician V.I.Kulakov of the Ministry of Healthcare of the Russian Federation

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/05/2023	22/05/2023	Yes	No

Protocol article	protocol	02/09/2021	13/10/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes