Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Investigating the effect of dexamethasone administration on the progress of labor in pregnant women referred to hospital

Protocol summary

Study aim
help to pregnant womens
Design
The control group with the parallel group of two randomized blinded phase 2 on 120 patients
Settings and conduct
besat hospital in1402 The pregnant mother and the midwife are unaware.
Participants/Inclusion and exclusion criteria
pregnant women
Intervention groups
control group and group that riceve drug
Main outcome variables
The amount of oxytocin consumed The amount of misoprostol consumed The distance between the latent phase and the start of the active phase The duration of the active phase of labor Cervical dilation rate The duration of the second stage of labor The time interval between induction and the birth of the baby

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231002059592N1**
Registration date: **2023-12-17, 1402/09/26**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-17, 1402/09/26**
Update count: **0**
Registration date
2023-12-17, 1402/09/26

Registrant information
Name
Sonia Ranjbar badrlo
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 87 3366 4832
Email address
dr.ranjbar3134@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-10-23, 1402/08/01
Expected recruitment end date
2024-03-20, 1403/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of dexamethasone administration on the progress of labor in pregnant women referred to hospital

Public title
Investigating the effect of dexamethasone administration on the progress of labor in pregnant women referred to Hospital .
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Term(37 w) nuli par cephalic
Exclusion criteria:
multi parati rupther of membran cpd(cephalopelvic disproportion) Iugr(intrauterin growth restrition) oligohydroaminus fetal distres
Age
No age limit

Gender
Female

Phase
0

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
simple block (patients are divided into four blocks equally between the intervention and control groups, then each block is given numerical tag codes, and finally, random numbers are selected from among the determined numbers using a random table and according to the determined blocks People are assigned to two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. In this way, pregnant women along with midwives who carry out drug orders are completely unaware. In this regard, sealed envelopes are used to allocate interventions.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kurdistan University of Medical Sciences

Street address
besat hospital

City
Sanandaj

Province
Kurdistan

Postal code
6619667761

Approval date
2023-05-14, 1402/02/24

Ethics committee reference number
IR.MUK.REC.1402.037

Health conditions studied

1

Description of health condition studied
Investigating the effect of dexamethasone administration on the progress of labor in pregnant women referred to Ba'ath Sanandaj Hospital in 1402

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Primary outcomes:1. The average number of received oxytocin units (measurements: during the entire active phase - variable measurement method: dropper and the number of oxytocin drops included in the medical record)2. The average number of misoprostol pills received (measurements: in the entire latent phase - how to measure based on the number of pills taken in the medical record)3. The average time interval between the latent phase and the start of the active phase of labor (measurement period: from the beginning of induction until reaching 5 to 6 cm dilatation - variable measurement method: vaginal examination)4. The average duration of the active phase of labor (measurement period: from dilation of 5 to 6 cm until dilation reaches 10 cm - method of variable measurement: vaginal examination)5. The average rate of cervical dilation (measurement interval: the rate of progress of cervical dilation every one hour from the start of induction to the dilation of 10 cm - how to measure the variable: partograph)6. The average duration of the second stage of labor (measurement period: from dilation of 10 cm to the complete exit of the fetus-variable measurement method: partograph)7. The average time interval between the beginning of induction of labor and the birth of the baby (measurement period: from the beginning of induction to the complete removal of the placenta and fetus-variable method of measurement: partograph)8. The average time interval of spontaneous rupture of the water bag

Timepoint
The time interval between birth according to the registry data until the time of entering the studyBy measuring the height and weight of the studied women and the result of dividing the weight by the square of the height in kilograms per square meterBased on the first ultrasound of the first trimester, the fetus contains FHRBaby weight at birth using a baby scale in gramsThe gender of the baby is girl or boyThe advance score is the scoring of the pregnant mother's vaginal examination to determine the type of treatment during childbirth. In this, scoring 5 parameters including 1) cervical dilatation 2) relaxation 3) station4) Consistency 5) The position of the cervix is given 0, 1, 2 and 3 points and then the total score of each mother before delivery is calculated.The amount and dose of oxytocin used is for the labor induction process.The amount and dose of misoprostol taken.The time interval between the beginning of induction of labor and the beginning of the active phase of labor (dilation of the cervix 5 to 6 cm) isThe time

interval between dilation of 5 to 6 cm and dilatation of 10 cm of the cervixThe rate of progression of cervical dilation every hour from the start of induction to the dilatation of 10 cm of the cervix.The time interval between dilatation of 10 cm and complete expulsion of the fetusThe time interval between the start of induction and the complete expulsion of the placenta and fetusThe causes of cesarean delivery include fetal heart failure, severe vaginal bleeding, endangering the life of the mother and fetus, descent or dilatation.The Apgar scale is a quick and reliable way to assess the health status of a newborn baby.Hospitalization of newborns after birth in the neonatal intensive care unitAny adverse medical event that is temporarily associated with the use of a medicinal product, safety and tolerability are evaluated based on the incidence of adverse events.1. Control group: pregnant mothers in this group receive oxytocin or misoprostol2. Latent phase group: pregnant mothers in this group receive intravenous dexamethasone and misoprostol.3. Active phase group: pregnant mothers in this group receive intravenous dexamethasone and oxytocin.Determining the time of mother's water sac rupture automatically

Method of measurement

According to the information completed by the person in the questionnaireAccording to the information completed by the person in the questionnaireUltrasound evaluation of the first trimesterAccording to the information completed by the person in the questionnaireAccording to the information completed by the person in the questionnaireEvaluation based on vaginal examination by a gynecologist/patient with a pre-test score of 6 or more receives oxytocin and a patient with a urine score of less than 6 receives misoprostolIt is calculated according to the injection amount by medical personnel.It is calculated according to the amount used by medical personnel.Evaluation using partograph and vaginal examinationEvaluation using partograph and vaginal examinationUsing a partographUsing a partographUsing a partographFollow-up and follow-up of the pregnant mother by a gynecologistFive simple criteria include appearance, pulse, crying, agile movements, and breathing pattern, each of which is numbered from zero to two, and after summarizing the overall health of the baby, it is determined.Newborn visit by gynecologistFollow-up and follow-up of the pregnant mother by a gynecologistBased on random allocationUsing a partograph

Secondary outcomes

1

Description

Secondary consequences:1. The frequency of cesarean delivery and its causes (measurement period: from the beginning of induction to the end of the study (throughout the study) - variable measurement method: being monitored by a gynecologist throughout the study)2. Neonatal outcomes including the average Apgar score of the first minute and the fifth minute (measuring periods: the first and fifth minutes after the birth of the baby - variable measurement method: it includes five components: 1) color, 2) heart rate, 3) reflexes, 4) muscle tone, and 5) respiration, each of which is scored 0, 1, or 2).3. The frequency of hospitalization of newborns in the intensive care unit (measurement periods: after the birth of the baby - variable measurement method: newborn visits by gynecologists)

Timepoint

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Intervention groups

1

Description

First, NST to evaluate fetal heart rate and TOCO to check uterine contractions as well as preliminary tests are taken from pregnant mothers. All patients undergo vaginal examination by the researcher and their urine and cervical dilatation scores are recorded. Then the demographic and clinical information of the patients including age, BMI, gestational age and sex of the fetus will be collected based on the checklist (Appendix 1). The mother's vital signs including heart rate, blood pressure, breathing rate and body temperature are checked and recorded in the medical record. After determining cervical dilatation, pregnant mothers are divided into 4 groups including two control groups, one latent phase group and one active phase group based on random blocks of 4. 1) Mothers in the latent phase control group who have dilation below 5 cm are treated with routine pregnancy induction drugs (misoprostol manufactured by Samisaz company 50 micrograms orally every 3 to 6 hours and normal saline 2 cc intravenously) and are subjected to vaginal examinations in the course of labor. When the mother enters the active phase, based on uterine contractions in the case of hypotonia, treated with intravenous oxytocin (half a milliunit per minute - manufactured by Caspian Company - until optimal uterine contractions are reached Mothers in the control group with the active phase, if they have a dilatation of more than 6 cm, if necessary (in case of hypotonia), are treated with intravenous oxytocin (according to the protocol mentioned above) and intravenous normal saline. 2 cc is placed until the desired uterine contractions are reached for delivery. 2) Pregnant mothers in the latent phase group are treated with intravenous dexamethasone at a dose of 8 mg (manufactured by Kimia Daru Company) and routine labor induction drugs (misoprostol orally 50 micrograms each 3 to 6 hours or EASI) until they reach the active phase, after entering the active phase, in case of hypotonia, they are treated with intravenous oxytocin (according to the protocol mentioned above) until they reach the optimal uterine contractions for delivery. take 3) Pregnant mothers in the active FAR group, who were initially treated with misoprostol or mechanical method, and who have reached 5-6 cm dilation, are treated with intravenous dexamethasone at a dose of 8 mg (manufactured by Kimia Daru Company) and, if necessary, oxytocin. IV is placed (according to the protocol mentioned above) until optimal uterine contractions are reached for delivery. It should be noted that during the course of labor, the mother's vital signs will be regularly checked by medical personnel according to the protocol and recorded in the file. In the event of any possible side effect or threat to the health of the mother and fetus, the treatment process is stopped and necessary measures are taken depending on the condition of the mother. During the study, the following outcomes will be evaluated, and after the birth of the baby, the baby's weight will be measured with a scale and recorded in the checklist (Appendix 1).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
besat hospital
Full name of responsible person
sonia ranjbar badrloo
Street address
besat hospital.sanandaj
City
sanandaj
Province
Kurdistan
Postal code
6619667761
Phone
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Fax
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Email
dr.ranjbar3134@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
sonia ranjbar badrloo
Street address
besat hospital sanandaj
City
sanandaj
Province
Kurdistan
Postal code
6619667761
Phone
+98 87 3328 5914
Email

dr.ranjbar3134@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sanandaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

sonia ranjbar badrloo

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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besat hospital.sanandaj

City

کردستان

Province

Kurdistan

Postal code

6619667761

Phone

+98 87 3328 5914

Email

dr.ranjbar3134@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

sonia ranjbar barloo

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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City

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Postal code

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dr.ranjbar3134@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

sonia ranjbar badrloo

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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dr.ranjbar3134@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available