Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Comparative study of the effects of TNG, misoprostol, dexamethasone and Foley catheter with acetaminophen on the process effacement and dilatation in the inactive and active phase of labor

Protocol summary

Study aim
Comparison of the effects of TNG, misoprostol, dexamethasone and Foley catheter on the process labor

Design
A single-blind clinical trial with a control group. Patients are randomly divided into 4 groups according to the above items. 60 patients in each group The method of randomizing the table of random numbers in vital statistics reference books is such that the numbers 1 to 50 belong to the first group, and the numbers 51 to 100 belong to the second group and the numbers 101 to 150 belong to the third group. Trial phase: It has no validity.

Settings and conduct
Then changes in fetal heart rate, mother's blood pressure, mother's heart rate, mother's breathing rate, random sugar in each group will be recorded before drug injection and 1 hour after the first dose and 2 hours after the first dose. In case of repeating the drugs, up to 3 doses of the above items are measured before and 1 hour and 2 hours after re-administration.The length of the active phase, the type of delivery, the baby's weight and the first and fifth minutes of Apgar and the umbilical cord ABG at the time of the baby's birth are recorded. In the whole study, all possible side effects for the mother and the baby are evaluated and checked very carefully, and if there is a possibility that it is related to the intervention, it is quickly reported to the ethics committee and the plan is temporarily stopped until re-approval.

Participants/Inclusion and exclusion criteria
Gravid 1 with GA > 37 weeks and Bishop score ≤ 4 and singleton pregnancy

Intervention groups
1-Cervical catheter is inserted into cervix. 2-Nitroglycerin: The contents of 400 micro TNG tablets poured into the cervix. 3-Dexamethasone: 8 mg is injected intramuscularly. 4-(Control) Misoprostol: 25 micrograms of misoprostol is placed sublingually.

Main outcome variables
Length of delivery; caesarean section rate; complications during childbirth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180409039247N3**
Registration date: **2022-12-20, 1401/09/29**
Registration timing: **prospective**

Last update: **2022-12-20, 1401/09/29**
Update count: **0**

Registration date
2022-12-20, 1401/09/29

Registrant information

Name
Marjan Ghaemibidgoli

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effects of TNG, misoprostol, dexamethasone and Foley catheter with acetaminophen on the process effacement and dilatation in the inactive and active phase of labor

Public title

Comparison of the effect of TNG, misoprostol, dexamethasone and Foley tube along with acetaminophen on the process of dilatation and effusion in childbirth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-40 years old Gestational age > 37 weeks Singleton pregnancy Cephalic presentation Gravid 1

Exclusion criteria:

Cephalopelvic incompatibility Maternal medical diseases Fetal distress Uterine scar Sensitivity to studied drugs

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomizing the table of random numbers is vital statistics reference books.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in the research of Imam Khomeini hospital complex

Street address

Imam complex, East Bagherkhan street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-11-15, 1401/08/24

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.226

Health conditions studied

1

Description of health condition studied

Increasing the success rate in vaginal delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The time interval of hospitalization for the termination of pregnancy until delivery

Timepoint

Every 6 hours

Method of measurement

Minutes

Secondary outcomes

1

Description

Reducing the cesarean rate

Timepoint

At the end of the labor phase

Method of measurement

Has she had a caesarean section?

Intervention groups

1

Description

Intervention group: The content of the 400 micro TNG tablet is diluted with 1 cc of serum and poured into the cervix (repeat after 4 and 6 hours if Bishop does not improve)

Category

Treatment - Drugs

2

Description

Intervention group: 8 mg of dexamethasone is injected

intramuscularly (this arm is one time and does not repeat)

Category

Treatment - Drugs

3

Description

Intervention group:The Foley catheter is inserted into the cervix with 500 ml of water (maximum 12 hours). Foley is 16 and the bottle is filled with 30 cc. If it does not turn off, it will automatically turn off after 12 hours.

Category

Treatment - Devices

4

Description

Control group: 25 microns of misoprostol is placed under the tongue (if Bishop does not improve over 4, it is repeated after 6 hours)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali-e-Asr hospital

Full name of responsible person
Fahimeh Ghotbizedeh

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East Bagherkhan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences - Research Assistant

Full name of responsible person
Akbar Fotouhi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences - Research Assistant

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
Tehran University of Medical Sciences

Full name of responsible person
Fahimeh Ghotbizadeh

Position
Associate professor

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Subspecialist

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Person responsible for updating data

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available