

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The safety and cost-effective of Isosurbidemononitrate prior to induction of labor

Protocol summary

Summary

The aim of this study is to determine that outpatient pre induction cervical ripening with Isosurbidemononitrate improves the process of induction of labor. Economic evaluation conducted a randomized placebo controlled trial. In zero phase , women who required labor induction for unfavorable cervixes (bishop score less than 6) each has singleton pregnancy with a Live fetus at least 37 weeks of gestation . In first phase, after examination, give their randomized study medication (either 2 Isosurbidemononitrate tablet or 2 placebo), to self -administers the tablet vaginally starting 24, 48 h before scheduled admission for induction of labor. In the second phase, women admit after trial medication, cervical status (Bishop Score) assess and labor induce with oxytocin protocol as per ACOG guidelines. We will analyze outcomes of elapsed time from hospital admission to vaginal delivery.

General information

Acronym

IMN

IRCT registration information

IRCT registration number: **IRCT201301134850N2**

Registration date: **2013-04-16, 1392/01/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-16, 1392/01/27

Registrant information

Name

Shokoh Alsadat Haji Seyed Abotorabi

Name of organization / entity

Qazvin,University of Medical Sciences & Health

Services

Country

Iran (Islamic Republic of)

Phone

+98 28 1369 0035

Email address

shabotorabi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice -chancellor for research, Qazvin university of medical sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The safety and cost-effective of Isosurbidemononitrate prior to induction of labor

Public title

The safety and cost-effective of Isosurbidemononitrate prior to induction of labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women have a singleton term pregnancy with a Live fetus; absence of uterine contractions and intact membranes. Exclusion criteria: fetal mal presentations; placenta previa; previous uterine incision or any contraindication of labor induction in ACOG

Age

To **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Science and health services

Street address

Shahid Bahonar Blvd

City

Qazvin

Postal code

Approval date

2013-01-08, 1391/10/19

Ethics committee reference number

28/20/6765

Health conditions studied

1

Description of health condition studied

termination of term pregnancy

ICD-10 code

O48

ICD-10 code description

Prolonged pregnancy

Primary outcomes

1

Description

Elapsed time induction of labor

Timepoint

Duration based on birth curves records

Method of measurement

Questionnaire

2

Description

Elpsed time interval from hospital admission to vaginal delivery

Timepoint

Based on the information entered in the records

Method of measurement

Questionnaire

Secondary outcomes

1

Description

parity

Timepoint

Age at admission

Method of measurement

Questionnaire

2

Description

age

Timepoint

Age at admission

Method of measurement

Questionnaire

Intervention groups

1

Description

self administration of Isosurbidemononitrate tablet vaginally starting 24,48 h before schedule admission .

Category

Treatment - Drugs

2

Description

self administration of placebo tablet vaginally starting 24,48 h before schedule admission .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital

Full name of responsible person

Dr Shokoh Sadat Haji Seyed Abotorabi , Obstetrics & gynecologist

Street address
khameneie Blvd
City
Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for research of Qazvin University of Medical Science
Full name of responsible person
Dr Sayed Assefzadeh
Street address
Post code 431102589, Plate 3, Shahid Bahonar Blvd, Qazvin City
City
Qazvin

Grant name

Grant code / Reference number

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

Title of funding source

Vice-chancellor for research of Qazvin University of Medical Science

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University Of Medical Sciences & Health Services
Full name of responsible person
Dr Shokoh sadat Haji Seyed Abotorabi
Position
Obstetrics & gynecologist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary

empty