Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of sublingual Misoprostol and Oxytocyn in labor duration

Protocol summary

Summary

82 patients were randomly selected. Subjects were randomly divided into two groups. In one group (41 persons) Oxytocin was given and in the other group (41 patients) 50 mg sublingual Misoprostol was administered. In the first group, in the case of inappropriate contractions, the starting dose of 1 mμ / min dose of Oxytocin was given every 15 min, until appropriate contractions started. In the second group 50 mg of sublingual Misoprostol was given .the patients did not received any other medicine, in first 6 hours after taking Oxytocin. Contractions of the patients were noted for their intensity and frequency, for 6 hours. If inappropriate contractions were observed after 6 hours, a starting dose of 1 mμ / min of Oxytocin was given every 15 min until appropriate contractions started. Finally, delivery improvement Bishop score of 8 and more, Apgar score, Meconium, delivery method, uterine activity and fetal distresses were recorded. Finally, all information obtained in each study group was evaluated and the data from the two groups were compared statistically.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013032512856N1**
Registration date: **2014-08-21, 1393/05/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-08-21, 1393/05/30

Registrant information

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2013-08-24, 1392/06/02

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of sublingual Misoprostol and Oxytocyn in labor duration

Public title

Comparison of the effects of sublingual Misoprostol and Oxytocyn

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: singleton pregnancy; first or second alive delivery; Bishop Score of 4 or more, no history of any internal disorders, age between 18 to 35 years old. Exclusion criteria: twin pregnancy and contraindications of induction.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences

City

Hamedan

Postal code

Approval date

2012-07-07, 1391/04/17

Ethics committee reference number

16/35/9/1279/پ/د

Health conditions studied

1

Description of health condition studied

Labor

ICD-10 code

O80

ICD-10 code description

Single spontaneous delivery

Primary outcomes

1

Description

Labor time

Timepoint

Before and after intervention

Method of measurement

Hour

Secondary outcomes

1

Description

Time to Bishop 8 and kind of delivery

Timepoint

After intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

In intervention group, in the case of inappropriate contractions, the starting dose of 1 mμ / min dose of Oxytocin was given every 15 min, until appropriate contractions started.

Category

Treatment - Drugs

2

Description

In the control group 50 mg of sublingual Misoprostol was given. The patients did not received any other medicine, in first 6 hours after taking Oxytocin.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh hospital of Hamedan

Full name of responsible person

Soghra Rabiee

Street address

Fatemieh hospital of Hamedan

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences, research department

Full name of responsible person

Saeed Bashirian

Street address

Fatemieh hospital of Hamedan

City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Sciences, research department
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
Hamedan University of Medical Sciences
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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