Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

Targeted therapy for threatened preterm labor based on sonographic measurements of the cervical length in women

Protocol summary

Study aim

This study to elucidate the role of cervical length measurement in prediction of preterm birth in those with threatened preterm labor.

Design

We included 120 women presenting with painful uterine contractions before 34 weeks of gestation randomly assigned to undergo measurement of cervical length (n=65) and to receive tocolysis. Those with cervical length <15 mm received tocolysis. However those with cervical length ≥15 mm were managed expectantly. Delivery within 7 days of presentation was the primary outcome.

Settings and conduct

this study to elucidate the role of cervical length measurement in prediction of preterm birth in those with threatened preterm labor. This was a randomized clinical trial being performed at Hafez Hospital of Shiraz University of Medical Sciences. We included 120 women presenting with painful uterine contractions before 34 weeks of gestation randomly assigned to undergo measurement of cervical length (n=65) and to receive tocolysis. Those with cervical length <15 mm received tocolysis. However those with cervical length ≥15 mm were managed expectantly. Delivery within 7 days of presentation was the primary outcome.

Participants/Inclusion and exclusion criteria

Women with cervical dilatation >5 cm, polyhydramnios, macrosomia, multiple pregnancy, suspected intrauterine infection, rupture of membranes, vaginal bleeding were excluded.

Intervention groups

65 patients undergoing cervical length measurement by transvaginal ultrasonography for further management (case group) and 55 patients who received tocolytic and corticosteroid therapy (control group)

Main outcome variables

cervical length, Delivery within 7 days

General information

Reason for update

Add results and modify some items

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092317034N5**
Registration date: **2017-10-16, 1396/07/24**
Registration timing: **retrospective**

Last update: **2023-12-06, 1402/09/15**
Update count: **1**

Registration date

2017-10-16, 1396/07/24

Registrant information

Name

Homeira Vafaei Cisakht

Name of organization / entity

Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 2365

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vafaeih@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2010-10-01, 1389/07/09

Expected recruitment end date

2015-02-01, 1393/11/12

Actual recruitment start date

2010-10-01, 1389/07/09

Actual recruitment end date

2015-02-01, 1393/11/12

Trial completion date

2015-02-01, 1393/11/12

Scientific title
Targeted therapy for threatened preterm labor based on sonographic measurements of the cervical length in women

Public title
Cervical length measurement for preterm labor

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
At least 4 contractions in 20 min interval Single pregnancy Gestational age before 34 weeks Maternal age 18-40 y

Exclusion criteria:
Polyhydramnios (amniotic fluid index greater than 24 cm) Macrosomia(estimated fetal weight >90th centile) Rupture of membranes Cervical dilatation >5 cm Multiple pregnancy Suspected intrauterine infection Vaginal bleeding (more than bloody show) Major medical disorders in mother Contraindicated for vaginal delivery(e.g. placenta previa) Non-reassuring fetal heart monitoring Fetal anomaly Any contraindication for administer of beta-sympathomimetic drugs and previous treatment with tocolytics/corticosteroid in this pregnancy

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **120**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the unit numbers, patients were randomly assigned to two groups using a computerized random digit generator.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients will receive A medication based on computerized random digit number in double blind method and a code will be allocated to each patient (1 to 120) that will be encoded at the end of the study. The patients and the designer and drug distributors are not aware of the drug pack. This study is the second phase of trial.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences، Zand Street، Shiraz

City
Shiraz

Province
Fars

Postal code
34786-71946

Approval date
2010-03-18, 1388/12/27

Ethics committee reference number
Ct-88-5026

Health conditions studied

1

Description of health condition studied
Threatened preterm labor

ICD-10 code
o60

ICD-10 code description
Preterm labour and delivery

Primary outcomes

1

Description
Transvaginal sonography

Timepoint
At the beginning of the enrollment and after persistent uterine contractions more than 4 hours

Method of measurement
Sonography

2

Description
Preterm birth

Timepoint
7 days after enrollment

Method of measurement
Delivery

Secondary outcomes

empty

Intervention groups

1

Description

Those who were assigned to the case group underwent transvaginal ultrasonography for measuring the cervical length by one expert obstetrician. Neither residents nor sonographers were not aware of this clinical trial. Those with cervical length <15 mm were received tocolytic (Nifedipne (tablet 10 mg manufactured by toliddaru Pharmaceutical Company) 20 to 30 mg orally initial loading dose, then followed 10 mg every 6 hours up to 48 hours with a maximum dose of 180 mg/day) and corticosteroid therapy according to the hospital protocol. Expectantly management was performed when cervical length was ≥15 mm, but with persistent uterine contractions more than 4 hr, another cervical measurement was performed by the same operator. If the cervical length was become <15 mm tocolytic and antenatal corticosteroids were given.

Category

Treatment - Drugs

2

Description

In 55 patients that were diagnosed with preterm labor pain without check cervical length, tocolytic and antenatal corticosteroids were given.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Hafez hospital
Full name of responsible person
Syedeh Marjan Hosseni
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Maternal- Fetal Medicine (Perinatology), Hafez Hospital, Chamran Ave., Shiraz, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Shiraz University of Medical Sciences
Full name of responsible person
Dr Basir Hashemi
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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
Vice chancellor for research of Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyedeh Marjan Hosseni
Position
Rezedent of Obstetrics & GYN
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Participant data file: Information and research data Ethic form: Complete the Ethic form by the patient
When the data will become available and for how long
Participant data file:2023Ethic form: 2023
To whom data/document is available
Participant data file: Researcher & Patient Ethic form: Patient
Under which criteria data/document could be used
Participant data file: participant's or legal guardian's are permitted for awareness of the results. Ethic form: participant's or legal guardian's are permitted for awareness of the results.
From where data/document is obtainable
Participant data file: Obstetrics and gynecology ward Shiraz university of medical sciences Ethic form: Obstetrics and gynecology ward Shiraz university of medical sciences
What processes are involved for a request to access data/document
Participant data file: Refer to Maternal Fetal medicine Research Center, request for result information. Ethic form: Refer to Maternal Fetal medicine Research Center, request for result information.
Comments

Trial results

Please tick if results have been published
Yes
Summary result posting date

2023-12-06, 1402/09/15

Table of baseline comparison

Participant flow diagram

Table of variable outcomes' results

Table of adverse events

First publication date

2017-11-01, 1396/08/10

Abstract of published paper

Background: Preterm labor and birth are associated with several neonatal complications including respiratory distress syndrome and intraventricular hemorrhage. Differentiating true and false labor pain is a dilemma to obstetricians. Objective: To elucidate the role of cervical length measurement in prediction of birth in pregnant women with threatened preterm labor. Materials and Methods: In this double blind randomized clinical trial, 120 women with gestational age <34 wk who presented painful uterine contractions randomly assigned to undergo measurement of cervical length. Patients were registered in the hospital and a unit number was given. Based on the unit numbers, patients were randomly assigned to two groups using a computerized random digit generator. All participants were managed accordingly (n=65) or to receive tocolysis as planned (n=55). Tocolysis was prescribed when cervical length was <15 mm while those with cervical length ≥15 mm were managed expectantly. Delivery within 7 days of the presentation was the primary outcome. Results: This RCT showed in case group, 78.9% of patient with cervical length <15 mm were delivered within 7 days and only 21.1% of them maintained their pregnancy. Of those with cervical length ≥15 mm, only 15.2% were delivered within the study period and the rest (84.8%) maintained their pregnancy (p<0.001). Conclusion: “Our results indicate that in women who presented preterm labor symptoms, cervical length measurement will result in decreased unnecessary tocolytic treatment. Women with cervical length ≥15mm should not receive tocolysis, however, withholding corticosteroid therapy in these patients needs further evidence.