Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A comparison between sublingual Misoprostol and intravenous Oxytocin for inducing labor in women at term

Protocol summary

Summary

Background:Promotin of normal vaginal delivery is effective on reducing cesarian section and then complications due to it. In this study efficacy of sub lingual Misoprostol will examine for induction of labor at term in compare with Oxytocin infusion in mirza khoochakkhan in 2010-2011 Methods: Seventy term-pregnant women with unfavourable cervix were randomized to sublingual Misoprostol or intravenous Oxytocin groups by blockig method after getting informed written consent Sublingual Misoprostol group (group A,n=35) (Searle company) received 25 µg four hourly to maximum of 5 doses. Administration was continued until cervix was ready for amniotomy, spontaneous rupture of membranes, or starting active phase. Oxytocin intravenous infusion (group B,n=35)(Caspian company) 10 U/lit, was was initiated at 1 mU/min and if necessary, stepped up by 1 mU/min every 15 minutes then continued at the same till delivery completed. Permanent monitoring was done in both groups and Contractures were controlled every 15 min for assessing need to increase medicine administration. Only in situation of ineffective contractures and after doing NST, an additional dose of Misoprostol was administered. Amniotomy was performed when active phase had been started (cervix dilatation => 3cm) and membrane was intact. Determination of latent phase duration and starting active phase was done by vaginal examination. Vital signs were recorded from starting contractures until one hour of placenta voiding. Promethazine (25 mg IM) for nausea and Pethidine (50 mg, IM) for pain were used if necessary. Conclusion: if sublingual Misoprostol is better than intravenous Oxytocin for induction of labor at term or not. specific targets: 1-comparing mean of latent phase between Misoprostol and oxytocin group 2- comparing mean of active phase between Misoprostol and oxytocin group 3-comparing mean of starting time of inducing labour till delivery between Misoprostol and oxytocin group 4-comparing prevalence of uterous hypertonicity between Misoprostol and oxytocin group 5- comparing prevalence of meconium staining between Misoprostol and oxytocin group 6- comparing prevalence of decreasing FHR between Misoprostol and oxytocin group 7- comparing mean of Apgar score in first minute after delivery between Misoprostol and oxytocin group 8-comparing mean of Apgar score in fifth minute after delivery between Misoprostol and oxytocin group 9-comparing prevalence of caesarian section between Misoprostol and oxytocin group

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205089636N1**
Registration date: **2012-05-28, 1391/03/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-05-28, 1391/03/08

Registrant information

Name
Laleh Ghadirian
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6641 9763
Email address
lghadirian@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor of research of Tehran University of

Medical Sciences

Expected recruitment start date
2011-11-19, 1390/08/28
Expected recruitment end date
2012-06-19, 1391/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparison between sublingual Misoprostol and intravenous Oxytocin for inducing labor in women at term

Public title
effect of sublingual Misoprostol in inducing labor
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria were gestational age 37 - 42 weeks, Bishop Score =< 4, Indication for labor induction, cephalic presentation, reactive NST. Exclusion criteria were Bishop score > 4), gestational age less than 37 and more than 42, non-vertex presentation, intrauterine demise, previous uterine surgery, oligo or polyhydramnios, intrauterine growth retardation, multiple pregnancy, clinical evidence of cardiopulmonary collapse, electrolyte abnormalities, severe pre-eclampsia/eclampsi, hepatitis, asthma, glaucoma and adrenal insufficiency ,
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
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
Ethics commitee of Tehran University of medical sciences
Street address
5 th floor- qods avenue- keshavarz Blv
City
Tehran
Postal code
Approval date
2011-11-19, 1390/08/28
Ethics committee reference number
1470

Health conditions studied

1

Description of health condition studied
Indication for terminating pregnancy with low Bishop score
ICD-10 code
P05-P08
ICD-10 code description
Disorders related to length of gestation and fetal growth

Primary outcomes

1

Description
Indication for terminating pregnancy with unfavorable contractures and cervix
Timepoint
Every 15 minutes
Method of measurement
Physical examination

Secondary outcomes

1

Description
Vaginal delivery vs caesarian section
Timepoint
At the end of delivery
Method of measurement
Patients medical record

Intervention groups

1

Description
Intervention group: sublingual Misoprostol
Category
Treatment - Drugs

2

Description
Control group: intravenous Oxytocin
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mirzakhoochakkhan Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research,Tehran University of Medical Sciences
Full name of responsible person
Dr Akbar Fotouhi
Street address
Keshavarz Blv, qods street, 5th floor
City
Tehran
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,Tehran University of Medical Sciences
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
Tehran University of Medical Sciences
Full name of responsible person
Laleh Ghadirian
Position
Preventive and Community Medicine Specialist
Other areas of specialty/work
Street address
Center for Academic and Health Policy
City
Tehran
Postal code
Phone
+98 913 314 1409
Fax
Email
lghadirian@razi.tums.ac.ir , lalehghadirian@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shirin Niroomanesh
Position
Obstetrician and Gynecologist
Other areas of specialty/work
Street address
Mirzakoochakkhan Hospital
City
Tehran
Postal code
Phone
+98 21 8889 7761
Fax
Email
drniromanesh@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Laleh Ghadirian
Position
Preventive and Community Medicine Specialist
Other areas of specialty/work
Street address
Center for Academic and Health Policy
City
Tehran
Postal code
Phone
Fax
Email
lalehghadirian@yahoo.com
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