Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

The effect of simultanous intramuscular injection of Atropin and Hyoscine on labor progress in primigravid pregnant women

Protocol summary

Summary

Aim of research is effect of simultaneous intramuscular injection of Atropin and Hyoscine on labor progress in primigravid pregnant women. The method of research is randomized double blind placebo controlled clinical trial. Study population are primigravida pregnant who come to Arak Taleghani Hospital. Inclusion criteria: primigravida; cephalic presentation; age of pregnancy 37-42 weeks; dilatation of cervix 3-4 cm; membrane rupture and clear; no use cardiovascular drags; no use analgesic. Exclusion criteria: meconium amniotic fluid; drug reaction or sensitivity; cephalopelvic disperoportion; macrosomia. 216 women randomly divided in 4 groups(intervention and control). One group(54 person) receive atropin 0/01mg/kg max(0/5 mg) single dose intramuscular. Second group (54 person) receive hyoscine 29 mg single dose intramuscular.Third group receive distilled water 1cc single dose intramuscular. Forth group receive atropin 0/01mg/kg max(0/5 mg) plus hyoscine 20 mg single dose intramuscular. Before intervention and one hour after intervention exam vaginally and measure progress of labor.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304284686N6**
Registration date: **2013-05-07, 1392/02/17**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2013-05-07, 1392/02/17

Registrant information

Name

Mehri Jamilian

Name of organization / entity

School of Medicine, Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Not enough for processing

Funding source

Arak University of Medical Sciences ,vice president of education and research

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2013-11-29, 1392/09/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of simultanous intramuscular injection of Atropin and Hyoscine on labor progress in primigravid pregnant women

Public title

The effect of simultanous intramuscular injection of Atropin and Hyoscine on labor progress in primigravid pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: primigravida; cephalic presentation; age of pregnancy 37-42 weeks; dilatation of cervix 3-4

cm; membrane rupture and clear; no use cardiovascular drags; no use analgesic. Exclusion criteria: meconium amniotic fluid; drug reaction or sensitivity; cephalopelvic dicperoportion; macrosomiya.

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **216**

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
Arak University of Medical Sciences

Street address
Basij Square

City
Arak

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
91-135-5

Health conditions studied

1

Description of health condition studied
labor progressr

ICD-10 code
O80.0

ICD-10 code description
cases with minimal or no assistance, with or without episiotomy delivery in a completely normal case

Primary outcomes

1

Description
labor progress

Timepoint
before intervation and one hour after intervation

Method of measurement
vajinal exam

Secondary outcomes

1

Description
drug side effects

Timepoint
before intervention and one hour ater intervention

Method of measurement
vajnal exam

Intervention groups

1

Description
First group(54 person) receive atropin 0/01mg/kg max(0/5mg) single dose intramascular

Category
Treatment - Drugs

2

Description
Second group (54 person) receive hyoscine 20mg single dose intramascular

Category
Treatment - Drugs

3

Description
Third group (54 person) receive distilled water 20mg single dose intramascular

Category
Treatment - Drugs

4

Description
Forth group(54 person) receive atropin 0/01mg/kg max0/5mg plus hyoscine 20mg single dose intramascular

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak University of Medical Sciences

Full name of responsible person
Mehri Jamilian

Street address
Taleghani Hospital

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medival Sciences

Full name of responsible person
Dr. Ashtiyani

Street address
Basij Square

City
Arak

Grant name

Grant code / Reference number

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

Title of funding source
Arak University of Medival 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
Arak University of Medical Sciences

Full name of responsible person
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Position
Board of Obstetric and Gynecology, Assistant Professor

Other areas of specialty/work

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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*