

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of simultaneous 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

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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 simultaneous intramuscular injection of Atropin and Hyoscine on labor progress in primigravid pregnant women

Public title

The effect of simultaneous 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 drugs; no use analgesic. Exclusion criteria: meconium amniotic fluid; drug reaction or sensitivity; cephalopelvic disproportion; macrosomia.

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 progress

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 intervention and one hour after intervention

Method of measurement

vaginal exam

Secondary outcomes

1

Description

drug side effects

Timepoint

before intervention and one hour after intervention

Method of measurement

vaginal exam

Intervention groups

1

Description

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

Category

Treatment - Drugs

2

Description

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

Category

Treatment - Drugs

3

Description

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

Category

Treatment - Drugs

4

Description

Fourth group(54 person) receive atropin 0/01mg/kg max0/5mg plus hyoscine 20mg single dose intramuscular

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 Medical 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 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
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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

