Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect Of Virtual Reality On Pain In Primiparity Women During Episiotomy Repair

Protocol summary

Summary

METHODS: This study is a randomized clinical trial with a control group. The aim of this study is to determine the effectiveness of virtual reality on episiotomy pain in primiparous women .The population of the study is primiparous women with eligibility criteria. The sample size is estimated to be 30 women who will be randomly allocated to the two treatment groups of 15 people (users of audiovisual glasses and routine injections with lidocaine) and a control group (routine injection of lidocaine). Pain will be measured with the Numeric Pain Rating Scale (0-10). During the four stages which are before repair, prescription of anesthesia (during repair of skin and Hymen), immediately and the first hour after of episiotomy repair. Inclusion criteria: Iranian people; primiparous; being in the active phase of labor (dilation 4-5 cm); pregnancy with single fetus; Cephalic presentation; Episiotomy incision; Apgar score of 7-10; no birth anomaly; no history of mental illness; mother addiction; no history of motion sickness; headache. It is excluded because of: impaired vision or hearing; prescription pain medication before or during episiotomy repair (except single dose of Lidocaine); any obstetric complications required emergency Aid.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811063185N1**
Registration date: **2013-12-01, 1392/09/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-12-01, 1392/09/10

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Research of Mashhad University of Medical Science Deneshghah Street, Mashhad, Khorasan Razavi, Iran.

Expected recruitment start date

2012-05-22, 1391/03/02

Expected recruitment end date

2012-07-20, 1391/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Virtual Reality On Pain In Primiparity Women During Episiotomy Repair

Public title

The Effect Of Virtual Reality On Pain During Suture Repair After Delivery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Iranian people; primiparous; being in the active phase of labor (dilation 4-5cm); pregnancy with single fetus; Cephalic presentation; Episiotomy

incision; Apgar score of 7-10; no birth anomaly; no history of mental illness; mother addiction; no history of motion sickness; headache. Exclusion criteria: Impaired vision or hearing; receiving pain medication before or during episiotomy repair (except single dose of Lidocaine); any obstetric complications required emergency Aid.

Age
From **18 years** old to **34 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

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
Mashhad University of Medical Sciences

Street address
Daneshghah street, Mashhad

City
Mashhad

Postal code

Approval date
2011-11-26, 1390/09/05

Ethics committee reference number
89600

Health conditions studied

1

Description of health condition studied
Episiotomy pain

ICD-10 code
O00-O99

ICD-10 code description
Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
Pain

Timepoint
During the four stages:1. before repair and prescription of anesthesia 2. during repair of skin and Hymen 3. immediately after repair 4.the first hour after repair.

Method of measurement
Numeric Pain Rating Scale

Secondary outcomes

1

Description
Blood pressure

Timepoint
Before and after episiotomy

Method of measurement
Sphygmomanometer

Intervention groups

1

Description
Intervention group: Use of audiovisual glasses + Standard prescription of anesthesia Control group : Standard prescription of anesthesia

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Omolbanin Hospital

Full name of responsible person
Farial Pabarja

Street address
Hasheminejhad Street

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Research of Mashhad University of Medical Science

Full name of responsible person
Dr. Mohamad Ramezani

Street address
Daneshghah Street,Mashhad

City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Research of Mashhad University of Medical Science
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
School of Nursing & Midwifery
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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