

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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

Name

Samira Ebrahimzadeh Zagami

Name of organization / entity

School of Nursing & Midwifery

Country

Iran (Islamic Republic of)

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ebrahimzadehzs@mums.ac.ir

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

000-099

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

Full name of responsible person
Nahid Jahani Shoorab

Position
Faculty member

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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