Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The evaluation of oral Bromelain (pineapple) on episiotomy pain and wound healing in primiparus women

Protocol summary

Summary

The aim of this study was to determine the effect of oral Bromelain on perineal pain and wound healing in primiparus women. In this double-blind clinical trial, 100 women with mediolateral episiotomy randomly received Bromelain, 100 mg (one tablet), starting at 2 hours after delivery, three times daily for six days or placebo. Episiotomy pain was measured by VAS scale at the first 24 hours, 3th, 7th, and 14th day and wound healing was measured by REEDA scale on 3th, 7th, and 14th day after delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810112952N1**
Registration date: **2010-02-27, 1388/12/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-02-27, 1388/12/08

Registrant information

Name

Samira Golozar

Name of organization / entity

Ahwaz Jondishapoor University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Jondishapur University of Medical Sciences, Ahwaz

Expected recruitment start date

2009-06-05, 1388/03/15

Expected recruitment end date

2009-10-22, 1388/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of oral Bromelain (pineapple) on episiotomy pain and wound healing in primiparus women

Public title

The effect of Bromelain on episiotomy pain and wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 to 35 years, Gestational age between 37 to 42 weeks, single pregnancy, cephalic presentation, Iranian nationality, residence in Ahvaz, Normal vaginal delivery, newborn Weight between 2500 to 4000 grams, medio-lateral episiotomy with 4-3 cm length, Education level at least the fifth grade, body mass index: 19/6-26, cervical dilation 3-5 cm Exclusion criteria: Diseases affecting wound healing (diabetes, kidney disease, anemia, liver diseases, cystocele or anxiety disorders), smoking and drug abuse, consumption of drugs affecting wound healing (glucocorticoids, anti-coagulatives, immune system suppressants, antibiotics or chemotherapy agents), abortion, premature rupture of membranes, having symptoms indicative of infection, anemia, rectum and vulva lesions, abnormal bleeding after childbirth, hematoma in the perineal operation, newborn anomaly,

dead baby, abnormal first, second or third delivery stage

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

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
Ahwaz Jondishapoor University of Medical Sciences

Street address
Ahwaz Jondishapoor University of Medical Sciences, Golestan Blvd.

City
Ahwaz

Postal code

Approval date
2009-07-11, 1388/04/20

Ethics committee reference number
3/8/20/1946

Health conditions studied

1

Description of health condition studied
Episiotomy

ICD-10 code
O90

ICD-10 code description
Complications of the puerperium, not elsewhere classified

Primary outcomes

1

Description
Pain

Timepoint
2 hrs after delivery, 24 hrs after delivery, 1 hr after consumption of initial dose, 3th, 7th, and 14th day after delivery

Method of measurement
VAS scale

Secondary outcomes

1

Description
wound healing

Timepoint
3th, 7th, and 14th day after delivery

Method of measurement
REEDA scale

Intervention groups

1

Description
Bromelain, 100mg (one tablet), starting from 2 hrs after delivery, three tims daily for six days

Category
Treatment - Drugs

2

Description
Placebo, one tablet, from 2 hrs after delivery, three times daily for six days

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin hospital

Full name of responsible person
Ms Dobahri Zadeh

Street address

City
Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research center of Jondishapur University of Medical Sciences

Full name of responsible person

Ms Jaderi

Street address

Jondishapur University of Medical Sciences, Golestan Blvd.

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Ahwaz

Grant name

Grant code / Reference number

u-88146

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

Yes

Title of funding source

Research center of Jondishapur 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

Ahwaz Jondishapoor University of Medical Sciences

Full name of responsible person

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Position

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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