Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effect of Anahil 500 (bromelain 500) and vitamin C on episiotomy wound healing in primiparous women

Protocol summary

Study aim
The effect of Anahil 500 (bromelain 500) and vitamin C on episiotomy wound healing in primiparous women.

Design
In a randomized clinical trial with the parallel control group, double-blind; Phase 2-3, on 240 patients; randomization is performed by using block randomization

Settings and conduct
In this double-blind clinical trial parallel study, 140 patients who are candidates for normal vaginal delivery in Fatemieh Hospital in Hamadan will be included in the study. The researcher who measures and records the consequences and the patients are unaware of the type of intervention performed, so the study is conducted in a double-blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 to 40 years; Gestational age between 37 to 42 weeks; single pregnancy; cephalic presentation 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: 19.8-26 kg/m2; Cervical dilation 3-5 cm Exclusion criteria: Diseases affecting wound healing; Smoking and drug abuse Consumption of drugs affecting wound healing (glucocorticoids, anti-coagulative, immune system suppressants, antibiotics, or chemotherapy agents); abortion; premature rupture of membranes; having symptoms indicative of infection; Anemia; abnormal first, second, or third delivery stage dead baby.

Intervention groups
bromelain 500mg (one tablet) 2 hours after delivery three times a day along with oral vitamin C 100mg one tablet and in the other three groups, bromelain tablets; Vitamin C or placebo alone for seven days after delivery.

Main outcome variables
Wound healing and pain intensity after delivery using visual scale pain and Rida scale up to 7 days after delivery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160523028008N25**
Registration date: **2022-08-16, 1401/05/25**
Registration timing: **prospective**

Last update: **2022-08-16, 1401/05/25**
Update count: **0**

Registration date
2022-08-16, 1401/05/25

Registrant information

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Name of organization / entity
Hamadan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Anahil 500 (bromelain 500) and vitamin C on episiotomy wound healing in primiparous women

Public title
The effect of Anahil 500 (bromelain 500) and vitamin C on episiotomy wound healing

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 to 40 years Gestational age between 37 to 42 weeks single pregnancy cephalic presentation Normal vaginal delivery newborn Weight between 2500 to 4000 grams Medio-lateral episiotomy with 4-3 cm lengt Education level at least the fifth grade, body mass index: 19.8-26 kg/m2 Cervical dilation 3-5 cm

Exclusion criteria:
Diseases affecting wound healing 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 abnormal first, second or third delivery stage dead baby

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple randomization method will be used to implement random assignment. In this way, 140 consecutive (from 1 to 1400) will be written individually on paper and will be placed in a container. Then, each of the participants in the trial is asked to randomly select one of these 140 numbers in the container containing the numbers. Individuals who have selected numbers from 1 to 35 will be assigned to group A ("Intervention group 1") and those who have chosen numbers 36 to 70 to group B ("Intervention group 2") those who have selected numbers 71 to 106 to group C ("Intervention group 3") and those who have selected numbers 107 to 1400 to group d (control group).

Blinding (investigator's opinion)
Double blinded

Blinding description
The researcher will be unaware of the type of intervention. The physician examining the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2022-07-23, 1401/05/01

Ethics committee reference number
IR.UMSHA.REC.1401.411

Health conditions studied

1

Description of health condition studied
Episiotomy

ICD-10 code
090

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

Method of measurement
VAS scale

2

Description
wound healing

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

Method of measurement

REEDA scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: bromelain 500mg (one tablet) (Salamat Permon Amin) 2 hours after delivery three times a day along with oral vitamin C 100mg one tablet (Elixir Pharmaceuticals) for seven days after delivery.
Category
Treatment - Drugs

2

Description
Intervention group: bromelain 500mg (one tablet) (Salamat Permon Amin) 2 hours after delivery three times a day for seven days.
Category
Treatment - Drugs

3

Description
Intervention group: oral vitamin C 100mg one tablet (Elixir Pharmaceuticals) for seven days after delivery.
Category
Treatment - Drugs

4

Description
Control group: Placebo, one tablet, from 2 hrs after delivery, three times daily for seven days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Shahla Nasrolahi
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is not a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available