Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study of effect of amninotic membrane in the treatment of chronic cervical infection in female patients admitted in Sanandaj Besat hospital

Protocol summary

Study aim
Determining the effect of amniotic membrane (amniodisc) in treatment of chronic cervical infection in female patients admitted in Besat Hospital in Sanandaj in 2024-2025

Design
The clinical trial has a control and intervention group, randomized open label trial is used to study 44 patients which have been divided completely randomly based on block randomization .

Settings and conduct
This study is conducted in the gynecology clinic of Besat Hospital, Sanandaj . volunteers with chronic cervical infection are included after examination based on the checklist of inclusion and exclusion criteria .Patients in the control group receive standard treatment for chronic cervicitis but for patients in intervention group amniotic membrane is used along with receiving standard treatment for chronic cervicitis . patients will be evaluated after one month .

Participants/Inclusion and exclusion criteria
Married women 18-50 years old Having vaginal discharge, lower abdominal pain, dysuria, vaginal odor, vaginal itching, dyspareunia, bleeding and pain after coitus. Women with severe inflammatory pap smear results Use of treatment for acute cervical infection before starting the study patients' tendency to participate in the study Exclusion criteria: 1- Single, pregnant and lactating women 2- People with reduced immune system due to illness or drug use 3-Having multiple sexual partners 4-Having acute cervical infection 5-Patients with cervical malignancies 6-People with mild to moderate inflammatory pap smear results

Intervention groups
In the intervention group, in addition to the standard treatment of cervicitis, the amniotic membrane is also used and visually examined by colposcopy for patients, and just the standard treatment of cervicitis is used for control group .

Main outcome variables
chronic cervical infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241007063283N1**
Registration date: **2025-01-14, 1403/10/25**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-14, 1403/10/25**
Update count: **0**

Registration date
2025-01-14, 1403/10/25

Registrant information

Name
Leila Taherabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 87 3328 2004

Email address
taherabadi81@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-22, 1403/08/01

Expected recruitment end date
2025-06-22, 1404/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of effect of amninotic membrane in the treatment of chronic cervical infection in female patients admitted in Sanandaj Besat hospital

Public title
Study of effect of amninotic membrane in the treatment of chronic cervical infection in female patients admitted in Sanandaj Besat hospital

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Married women 18-50 years old Having vaginal discharge, lower abdominal pain, dysuria, vaginal odor, vaginal itching, dyspareunia, bleeding and pain after coitus. Women with severe inflammatory pap smear results Use of treatment for acute cervical infection before starting the study patients' tendency to participate in the study

Exclusion criteria:
Single, pregnant and lactating women women with reduced immune system due to illness or drug use Having multiple sexual partners Having an acute cervical infection Patients with cervical malignancies women with mild to moderate inflammatory pap smear results

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided completely randomly based on block randomization.

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
Ethics Committee of Kurdistan University of Medical Sciences

Street address
Pasdaran Blvd,

City
Sanandaj

Province
Kurdistan

Postal code
6617715175

Approval date
2024-09-03, 1403/06/13

Ethics committee reference number
IR.MUK.REC.1403.124

Health conditions studied

1

Description of health condition studied
Chronic cervicitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Cervical infection

Timepoint
Before the intervention and one month after the intervention

Method of measurement
Examination by a doctor, Pap smear, and colposcopy image viewing

Secondary outcomes

empty

Intervention groups

1

Description
intervention group : Amniotic membrane is the main intervention in this study . by using inclusion and exclusion criteria and after examination by a doctor Patients are involved . the patients will be undergoing standard cervical treatment along with receiving prepared amniotic membrane patches provided by Sinacell co. for using on the cervix .

Category
Treatment - Other

2

Description
Control group : In this group, patients will be undergoing standard cervical treatment after confirming cervicitis

through examination and after entering the study using the inclusion and exclusion criteria.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology Clinic, Besat Hospital, Sanandaj

Full name of responsible person

Leila taherabadi

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Keshavarz Ave .

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Sanandaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr. afshin maleki

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6617913446

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+98 87 3366 4643

Email

paralib@muk.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj University of Medical Sciences

Proportion provided by this source

20

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

2

Sponsor

Name of organization / entity

Sinacell Manufacturing - Research Company

Full name of responsible person

Maryam mahmudiniya

Street address

Sinacell co. No 162 , Noavari 16th street. Pardis science and technology park Jajrud road

City

Tehran

Province

Tehran

Postal code

1654120596

Phone

+98 21 7625 0661

Email

Info@Sinacellco.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sinacell Manufacturing - Research Company

Proportion provided by this source

80

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Leila Taherabadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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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
The result of the study is not related to the publication of individual data
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available