

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Relationship between serum estradiol levels and topical estrogen cream used in girls with labial adhesions

Protocol summary

Summary

Introduction and aims: Proper treatment of labia adhesion is important because of increasing risk of urinary tract infection in the presence of other risk factors. In addition, a serum level of estradiol in those patients is still controversial. This study investigated the relationship between serum estradiol levels and topical estrogen cream in labia adhesion. Methods and materials: This double-blind clinical trial was performed in Taleghani Hospital in Gorgan city at 2010. 3-08 months children with more than 25% adhesion Labia were treated with topical estrogen cream, in one week. Blood estradiol levels were measured before and after treatment and evaluated based on response to treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012121611560N1**

Registration date: **2013-01-31, 1391/11/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-31, 1391/11/12

Registrant information

Name

Tayeb Ramim

Name of organization / entity

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University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Gorgan University of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2012-04-01, 1391/01/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Relationship between serum estradiol levels and topical estrogen cream used in girls with labial adhesions

Public title

Relationship between serum estradiol levels and topical estrogen cream used in girls with labial adhesions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: age between 3 months and 8 years; no puberty ; labia adhesion >25%; no vulvagenitis.

Exclusion Criteria : no use of Drug; no follow up; adverse drug reaction.

Age

To **9 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Gorgan University of Medical Sciences

Street address
Imam Khomeini Sq

City
Gorgan

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
15991012902

Health conditions studied

1

Description of health condition studied
Minor Labial Adhesion

ICD-10 code
N90.8

ICD-10 code description
Adhesions of vulva

Primary outcomes

1

Description
release of adhesion

Timepoint
7 days

Method of measurement
Clinical Examination

Secondary outcomes

1

Description
no urinary track infection

Timepoint
3 month

Method of measurement
clinical Examination; history

Intervention groups

1

Description
EQUIN conjugated estrogens USP, 0.625 mg/g, Spain, daily, seven days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Gorgan University of Medical Sciences

Full name of responsible person
Dr. Baranak Safaian

Street address
Pediatrics Ward, Taleghani Hospital, Imam khomeini St

City
Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology

Full name of responsible person
Dr. Shahryar Semnaneh

Street address
Imam Khomeini st.

City
Gorgan

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for Research and Technology

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

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Person responsible for general inquiries

Contact

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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