

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison of the effect of (*Salvia officinalis* L.) ointment and common treatment on diaper-induced dermatitis in children

#### Protocol summary

Intensity, extent, pain and duration of dermatitis recovery

#### Study aim

Determine the effect of (*Salvia officinalis* L.) ointment and common treatment on intensity, extent, pain and duration of diaper-induced dermatitis.

#### Design

This study will be a clinical trial with a control group, with parallel groups, double-blind, randomized allocation and phase 2 on 60 infants. In phase 1, the ointment is tested on 6 to 8 infants, which is performed in the next phase if it has beneficial therapeutic effects.

#### Settings and conduct

Samples are selected from children under 2 years of age admitted to different wards of children in Imam Sajjad Hospital in Yasuj, who, according to the clinical diagnosis of a pediatrician, have degrees of diaper dermatitis using non probability convenience sampling method. After obtaining the informed consent of each patient, they are randomly assigned to one of the two intervention and control groups.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Children under two years old. 2- Use disposable diapers or disposable pads. 3. Do not have known immune system weakness. 4- Do not receive drugs that weaken the immune system. 5 - Lack of special food and drug allergies. 6. Do not have special skin allergies. 7- Do not suffer from extensive skin infections. 8- Parents should be willing to participate in the study. Exclusion criteria: 1. Discontinue treatment or change it for any reason during the treatment period. 2- In case of occurrence and identification of a new problem affecting the child's rash. 3- People who take care of a new drug and especially a plant to treat dermatitis.

#### Intervention groups

The intervention group includes children with diaper dermatitis who receive (*Salvia officinalis* L.) ointment intervention. The control group includes children with diaper dermatitis who receive routine treatment intervention.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190120042436N3**

Registration date: **2020-11-10, 1399/08/20**

Registration timing: **prospective**

Last update: **2020-11-10, 1399/08/20**

Update count: **0**

##### Registration date

2020-11-10, 1399/08/20

##### Registrant information

###### Name

Mohsen Salari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 74 3323 4115

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salarimo@yums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2020-11-21, 1399/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of (Salvia officinalis L.) ointment and common treatment on diaper-induced dermatitis in children

**Public title**

Effect of (Salvia officinalis L.) ointment on diaper-induced dermatitis in children

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

1. Children under two years of age 2 - use disposable diapers or disposable pad. 3. Lack of recognized immune system weakness. (based on the physician diagnosis.)4. do not use certain drugs to suppress immune system5- Lack of specific food and drug allergies 6 - Lack of specific skin sensitivity. 7. Lack of extensive skin infections 8 - Parents tend to participate in the study.

**Exclusion criteria:**

1. Discontinue treatment or change treatment for any reason during the treatment period. 2- In case of occurrence and identification of a new problem affecting the child's rash. 3-People who take care of a new drug and especially a plant to treat dermatitis.

**Age**

From **1 day** old to **2 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Based on a simple random method, each person who meets the inclusion criteria is assigned to one of the two groups of intervention or routine treatment by lot.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the participants do not know that they are in which of the groups under study, while the ward nurse as a clinical caregiver and the doctor as an outcome assessor does not know the type of interventions performed for patients. The data analyzer also does not know the allocation of study groups because it will be specified as A and B.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Yasuj University of Medical Sciences

**Street address**

Shahid Jalil Street. Educational Pardis, Yasuj.

**City**

Yasuj

**Province**

Kohgiluyeh-va-Boyerahmad

**Postal code**

94799 - 75919

**Approval date**

2020-07-08, 1399/04/18

**Ethics committee reference number**

IR.YUMS.REC.1399.106

**Health conditions studied****1****Description of health condition studied**

Diapper Rash

**ICD-10 code**

L22

**ICD-10 code description**

Diaper dermatitis

**Primary outcomes****1****Description**

Percentage of people whose severity and extent of dermatitis is equal to or greater than average based on checklists.

**Timepoint**

The beginning of the study, the second, fourth and sixth day after starting treatment

**Method of measurement**

A five-point scale is used to measure the severity and extent of diaper rash, and a Modified Behavioral Pain Scale is used for pain.

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: Treated with Salvia officinalis L. ointment which contains 28% hydroalcoholic extract of the aerial part of the plant contains leaves, flowers and stems and similar to Salvizan gel. After washing and drying the dermatitis area, depending on the extent of dermatitis, this ointment will be used 3 times a day for a maximum of 7 days to cover the surface of the dermatitis skin (1 Centimeter).

### Category

Treatment - Drugs

## 2

### Description

Control group: Treated with routine treatment (Zinc oxide and Hydrocortisone Ointments). Depending on the extent of dermatitis, these ointments will be used 3 times a day for a maximum of 7 days to cover the surface of the skin (1 Centimeter).

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Sajjad Hospital

##### Full name of responsible person

Dr. Nikbakht; Dr. Abdolkarim Ghadimimoghadam

##### Street address

Kohgiluyeh and Boyer Ahmad, Yasuj, next to Azadi Hotel

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Yasuj

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##### Web page address

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Dr. Hossein Mari Oryad

##### Street address

Shahid Motahari Blvd., Vice Chancellor of Research,  
Yasuj University of Medical Sciences, Yasuj

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##### Web page address

<http://research.yums.ac.ir/index.aspx?siteid=11&fkeyid=&siteid=11&pageid=9397>

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Yasouj 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

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Dr. Mohsen Salari

##### Position

Ph.D. Pediatric Nursing

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

Shahid Dr. Jalil St., Nursing School of Hazrat Zaynab (SA), Yasuj, Iran

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Malihe Rezaei

**Position**

Master student in pediatric nursing

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**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**

Undecided - It is not yet known if there will be 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