

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluation of Acacia Senegal Gum Effect on Prevention And Treatment of Peristomal Skin Disorder in Children in alzahra hospital , Isfahan, IRAN 2010-2011

#### Protocol summary

##### Summary

AIM: to evaluate the effect of acacia Senegal gum in treatment/management of the ostomy complications of the peristomal skin area defects, skin situation (chemical irritation and mechanical trauma). METHODS: a ll children with stoma and peristomal skin disorder were eligible to participating in my research: 10 patients were observed for 8 months (5-under effect of acacia Senegal gum, 5- under effect of zinc oxide ointment.We used acacia Senegal gum to prevention and treatment of peristomal skin disorder in trial group and zinc oxide ointment as same in control group to comparison the wound skin healing in each group. We use the acacia Senegal gum and zinc oxide in order to understand the effectiveness of material within period of 8 days .The clinical observation methods with especial assessment tools DET and get Photograph) were used. The peristomal complications were positively influenced by the use of the acacia Senegal gum . The effect of acacia Senegal gum in compare to zinc oxide for treatment of peristomal skin disorders almost thesame

#### General information

##### Acronym

Peristomal Skin Complication

##### IRCT registration information

IRCT registration number: **IRCT201112178431N1**

Registration date: **2013-11-13, 1392/08/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-11-13, 1392/08/22

##### Registrant information

##### Name

Afsaneh Pirnia Naeini

##### Name of organization / entity

Alzahra Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1668 5555

##### Email address

afsaneh@stu.kanazawa-u.ac.jp

##### Recruitment status

**Recruitment complete**

##### Funding source

National Research Council of Isfahan University Approved

With Given Main Money

##### Expected recruitment start date

2010-09-23, 1389/07/01

##### Expected recruitment end date

2011-03-21, 1390/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Acacia Senegal Gum Effect on Prevention And Treatment of Peristomal Skin Disorder in Children in alzahra hospital , Isfahan, IRAN 2010-2011

##### Public title

Evaluation of Acacia Senegal Gum Effect on Prevention And Treatment of Peristomal Skin Disorder in Children

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria : The children with ostomy who are

hospitalized in pediatric ward of AL Zahra hospital Isfahan province in Iran and exclusion criteria was patient that refuse to be under of our study ; patient with congenital sensitive skin

#### **Age**

From **1 year** old to **18 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **10**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Isfahan University of Medical Sciences.Vice Chancellor for Research

##### **Street address**

Isfahan University of Medical Sciences.Hezar Jarib Street

##### **City**

Isfahan

##### **Postal code**

8174675731

#### **Approval date**

2008-05-11, 1387/02/22

#### **Ethics committee reference number**

287239

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Peristomal Skin Disorder

#### **ICD-10 code**

K91.4

#### **ICD-10 code description**

Colostomy and enterostomy malfunction

## **Primary outcomes**

### **1**

#### **Description**

Treatment of Peristomal Skin Disorder in Area and Severity

#### **Timepoint**

every 2 days follow up for 8 days

#### **Method of measurement**

Check List(DET Score),Photography Sizing in AUTO CAD

### **2**

#### **Description**

Measurement of wound skin healing

#### **Timepoint**

2 days

#### **Method of measurement**

Autokad Softwaer and Photography

## **Secondary outcomes**

### **1**

#### **Description**

Wound Healing

#### **Timepoint**

Days Zero.Two.Four.Six.Eight

#### **Method of measurement**

DET Scoring Check List and Take Photograph and AUTO CAD analysis

### **2**

#### **Description**

Wound Healling

#### **Timepoint**

2 Days

#### **Method of measurement**

Auto Kad Softwaer and Photography

## **Intervention groups**

### **1**

#### **Description**

We used 3 gr Acasia Senegal Gum resolved in 20 ml pure water in control group for treatment of peristomal skin disorder in intervention group

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

For control group we cover 3 time a day all site of skin disorder with zinc oxide oitment and observed the skin wound healing

#### **Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Afsaneh Pirnia Naeini

**Street address**

Alzahra Hospital Standard and Evaluation Unit

**City**

Isfahan

### 2

#### Recruitment center

**Name of recruitment center**

Alzahra University Hospital

**Full name of responsible person**

Afsaneh Pirnia Naeini

**Street address**

Sofeh Avenue

**City**

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Isfahan University of Medical Sciences .Vice chancellor for research

**Full name of responsible person**

Mr.Moradi

**Street address**

Isfahan University of Medical Sciences

**City**

Isfahan

**Grant name**

داراي کد تصویب طرح به شماره 287239 به تاریخ 22/2/1378

**Grant code / Reference number**

287239

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

Yes

**Title of funding source**

Isfahan University of Medical Sciences .Vice chancellor for research

**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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Afsaneh Pirnia Naeini

**Position**

Master of Nursing / Accreditation Standards in Hospital

**Other areas of specialty/work****Street address**

Sofeh street.Alzahra Hospital

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Isfahan University of Medical Sciences.school of Nursing and Midwifery

**Full name of responsible person**

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**Position**

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## Person responsible for updating data

### Contact

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**Web page address****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*