

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effect of family-centered care and the needs of the anxiety parents of children with urinary tract infection

#### Protocol summary

##### Summary

This research is a semi - experimental study that determines the effect of family-centered care on the level of satisfying parents' needs on hospitalized children. The research site is the Pediatric ward of pediatrics medical training center in Rasht and the research population is mothers of hospitalized 1 to 3-year-old children suffering from UTI. Children with a history of hospitalization will be excluded. Sequential sampling is used each group is estimated to contain 35 subjects. The testimonial papers together with research objective were given to Case and Control groups. For control group, the ward routines care and for case group family-centered care protocol performed. Questionnaire will be completed by co-researcher pre and 48 hours after intervention. Questionnaire with 36 items is consisted of six areas of parent's needs including: needs to support and guidance, consultation, mutual confidence, obtaining information, comfort, convenience, communicating, and needs related to spouse and other family members.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016010625843N2**

Registration date: **2016-04-09, 1395/01/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-09, 1395/01/21

##### Registrant information

##### Name

Hajar Sadeghi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3503

##### Email address

haj.sadeghi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2015-02-22, 1393/12/03

##### Expected recruitment end date

2015-09-23, 1394/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of family-centered care and the needs of the anxiety parents of children with urinary tract infection

##### Public title

Family-centered care compared with usual care in reducing anxiety prevalent in parts of the hospital and meet the needs of patients and their families

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: only Children 1 to 3 years; To be suffering from UTI; Carer is the mother only; Mother has literacy to reading and writing. Exclusion criteria: Children with a history of hospitalization.

##### Age

From **1 year** old to **3 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **70**

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

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
The randomization is based on the table of random numbers.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Arak, Sardasht, Faculty of nursing and midwifery, Arak University of Medical Science

##### City

Arak

##### Postal code

#### Approval date

2015-02-20, 1393/12/01

#### Ethics committee reference number

93-169-17

## Health conditions studied

### 1

#### Description of health condition studied

Urinary tract infection

#### ICD-10 code

N39.0

#### ICD-10 code description

Urinary tract infection, site not specified

## Primary outcomes

### 1

#### Description

Anxiety and parental needs of hospitalized children

#### Timepoint

Before and 48 hours after intervention

#### Method of measurement

kristjansdottir standard questionnaire, Spielberger

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: For intervention group a family-centered care protocol are carried out which is prepared with the contribution of researcher, co-researcher and families as well as reviewing related books and articles. Before intervention, and after proper communication with the child, necessary information on care during hospital stay and after discharge is provided by nurses. Purpose of partnership in child care includes: feeding, clothes and diapers changing, taking axillary temperature, controlling intake and output, cleaning child buttocks, changing sheet and arranging child environment, and giving oral medications.

#### Category

Other

### 2

#### Description

Control group: Control group receive routine cares.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amirkabir hospital

##### Full name of responsible person

Hajar Sadeghi

##### Street address

Arak, Nurse Sq, Alamolhoda St, Amir kabir Hospital

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Arak University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Rafiee

##### Street address

Arak, Rahahan Sq, Alamolhoda St, Arak University of  
Medical Sciences

**City**

arak

**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 of Arak University of Medical  
Sciences

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Hajar Sadeghi

**Position**

MSC

**Other areas of specialty/work**

**Street address**

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## Person responsible for updating data

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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*