Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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 writting. 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, Saculty 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
Befor 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

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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