Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of topical ketoconazole in preventing fungal peritonitis in children undergoing peritoneal dialysis

Protocol summary

Study aim

Evaluating the effectiveness of topical use of 2% ketoconazole shampoo in preventing fungal peritonitis in children with peritoneal dialysis in Dr. Sheikh Mashhad Hospital .

Design

This research is a non-blinded randomized clinical trial study on 40 patients undergoing peritoneal dialysis in Dr. Sheikh Mashhad Hospital in 1402 and 1403 and the effectiveness of topical use of 2% ketoconazole shampoo in preventing fungal peritonitis

Settings and conduct

All children undergoing dialysis at Dr. Sheikh's peritoneal clinic who meet the inclusion criteria and are between the ages of 6 and 18 will be included in the study after obtaining informed consent. During one year, the patients randomly receive prophylaxis using ketoconazole weekly and topically on the abdominal skin, which is by washing with 2% ketoconazole shampoo. And culture of peritoneal return fluid in terms of fungi and bacteria is taken from the patients before starting shampoo and then after three months and after 6 months.

Participants/Inclusion and exclusion criteria

All children undergoing dialysis at Dr. Sheikh's peritoneal clinic are between the ages of 6 and 18.

Intervention groups

Patients in an intervention group will receive non-random ketoconazole prophylaxis weekly using 2% ketoconazole shampoo, smear and culture of peritoneal return fluid for fungi and bacteria before starting teken shampoo and after three months and after 6 months from the patients. The control group is the same group that did not receive prophylaxis in the last year.

Main outcome variables

Evaluating the effectiveness of topical use of 2% ketoconazole shampoo in preventing fungal peritonitis in children with peritoneal dialysis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231111060021N1**
Registration date: **2023-11-26, 1402/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-26, 1402/09/05**
Update count: **0**

Registration date

2023-11-26, 1402/09/05

Registrant information

Name
Mahdieh Nejatian
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3878 4344
Email address
nejatianm971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of topical ketoconazole in preventing fungal peritonitis in children undergoing peritoneal dialysis

Public title
Investigating the effect of topical ketoconazole in preventing fungal peritonitis in children undergoing peritoneal dialysis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Children undergoing peritoneal dialysis Absence of underlying skin diseases based on initial clinical evaluation Not have fungal peritonitis Informed consent Age 6 to 18 years
Exclusion criteria:
Diffuse infection requires receiving broad_spectrum antibiotics Having an open wound at the exit site of the catheter Need to change the catheter Incidence of skin sensitivity with topical ketoconazole
Age
From **6 years** old to **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Not randomized
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
e.g. Ethics committee of Mashhad University of Medical Sciences
Street address
Faculty of Medicine, Mashhad University of Medical Sciences, Kalantari Highway., Town Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177857984
Approval date
2023-08-28, 1402/06/06
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.272

Health conditions studied

1

Description of health condition studied
Child– Ketoconazole – Fungal Peritonitis – Chronic Peritoneal Dialysis.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Evaluating the effectiveness of topical use of 2% ketoconazole shampoo in preventing fungal peritonitis in children with peritoneal dialysis.
Timepoint
Smear and culture of peritoneal fluid for fungi and bacteria are taken from patients before shampooing and after three months and after six months.
Method of measurement
Returned peritoneal fluid culture and smear.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Control group(s) (placebo, no placebo):The control group is the same group that did not receive prophylaxis in the last year
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Sheikh Hospital
Full name of responsible person
Mahdieh Nejatian
Street address
Dr. Sheikh Children's Hospital, Dr. Sheikh Street, Tohid Sq.
City
Mashhsad

Province
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Postal code
9177857984
Phone
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Email
Nejatianm971@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Sara Saadat
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Sheikh.hos@mums.ac.ir
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https://sheikh.mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Sara Saadat
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatric Nephrology
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Person responsible for updating data

Contact
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Mashhad University of Medical Sciences
Full name of responsible person
Mahdieh Nejatian
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Medical Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Various methods have been recommended to prevent catheter exit infection, including catheter site care methods and prophylaxis with local antibiotics, but the use of antifungal drugs is not common. (2, 3). Ketoconazole is an antifungal drug that has been used since 1981 in the clinic. This drug prevents the growth and reproduction of fungi by inhibiting the synthesis of fungal ergosterol. The spectrum of effects of ketoconazole in systemic use includes Candida species (except C. glabrata), Malassezia and skin dermatophytes (4, 5). Due to the extensive side effects of ketoconazole including hepatotoxicity, adrenal disorders, and important drug interactions (through inhibition of the CYP450 3A4 enzyme), the use of this drug in the clinic is currently limited to cases where other antifungal drugs cannot be prescribed (6). Topical ketoconazole is effective against skin fungal infections and systemic side effects are not observed.The topical medicinal forms of ketoconazole include 1% and 2% shampoo, cream, foam and 2% gel, of which the common medicinal form in Iran is 2% shampoo.
When the data will become available and for how long
During one year, the patients randomly receive prophylaxis using ketoconazole weekly and topically on the abdominal skin, which is by washing with 2% ketoconazole shampoo. The shampoo brand is Iran Najo, and the cost of the shampoo is 12,000 Tomans, which is given from the Pezohashi grant. And culture of peritoneal return fluid in terms of fungi and bacteria is taken from the patients before starting shampoo and then after three months and after 6 months. If there are clinical symptoms of peritonitis, turbidity of peritoneal return fluid, abdominal pain, fever, immediately culture and smear of return peritoneal fluid in terms of fungus and bacteria is sent. Will be During this period, there is prophylaxis with mupirocin for all patients, which is part of the standard prophylaxis treatment of Verotin.The control group of these patients is the same group before using 2% ketoconazole shampoo. Informed consent is obtained from the legal guardian of the patients. Ketoconazole shampoo side effects include skin irritation and itching, oily or dry skin, abnormal hair texture or hair discoloration. Rarely possible. Does this drug cause hair loss. Allergic reactions to ketoconazole are very rare, but should be taken seriously. In case of allergic symptoms such as severe itching and swelling in the face, tongue or throat, shortness of breath and skin rashes, dizziness, stop using shampoo and the patient will be excluded from the study.
To whom data/document is available
All children undergoing dialysis at Dr. Sheikh's peritoneal clinic who meet the inclusion criteria and are between the ages of 6 and 18 will be included in the study after obtaining informed consent.Peritoneal Dialysis Department of Dr. Sheikh Hospital.
Under which criteria data/document could be used
Criteria for entering the study: Age 6 years to 18 years Receiving peritoneal dialysis Absence of underlying skin diseases based on initial clinical evaluation Not having fungal peritonitis Informed consent
From where data/document is obtainable
Peritoneal Dialysis Department of Dr. Sheikh Hospital
What processes are involved for a request to access data/document
The time required to reach this sample size: 12 months Intervention / exposure / main outcome group: Patients in an intervention group will receive non-random ketoconazole prophylaxis weekly using 2% ketoconazole shampoo, smear and culture of peritoneal return fluid for fungi and bacteria before startingTaken shampoo and after three months and after 6 months from the patients.
Comments