Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The prevalence of antibiotic resistance in pediatrices (3-15 years old) with streptococcal pharyngitis

Protocol summary

Study aim
General Objective: To determine the prevalence of streptococcal resistance in children with streptococcal pharyngitis

Design
Clinical trial with parallel, non-random, phase 2 groups on 310 patients

Settings and conduct
In this study, 310 children with symptoms of pharyngitis were studied. After receiving the result of pharyngeal 24-hour culture, patients who had a positive culture, ie Streptococcus pharyngitis group A was confirmed, were treated with antibiotics and were included in the study. All positive cultures were evaluated for antibiotic resistance to azithromycin, penicillin, clindamycin, and amoxicillin (antibiogram review).

Participants/Inclusion and exclusion criteria
inclusion criteria: 1- No history of tonsillectomy 2- Do not take antibiotics in the last two weeks 3- No complaints and symptoms of upper respiratory infection (cough, sneezing and runny nose) 4- Justification of the patient or his family and patients' desire to participate in the study. exclusion criteria: Patients under 3 years of age or over 15 years of age are not included in the study.

Intervention groups
Intervention group 1 includes patients receiving penicillin antibiotic and then pharyngeal culture to evaluate resistance. Intervention group 2 includes patients receiving azithromycin antibiotic and then pharyngeal culture to evaluate resistance. Intervention group 3 includes patients receiving clindamycin antibiotic and then pharyngeal culture to evaluate resistance. Intervention group 4 includes patients receiving amoxicillin antibiotic and then pharyngeal culture to evaluate resistance.

Main outcome variables
Determination of antibiotic resistance to the studied antibiotics and better treatment choice

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200720048140N1**
Registration date: **2020-07-27, 1399/05/06**
Registration timing: **retrospective**

Last update: **2020-07-27, 1399/05/06**
Update count: **0**

Registration date
2020-07-27, 1399/05/06

Registrant information
Name
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-05-22, 1397/03/01
Expected recruitment end date
2019-03-20, 1397/12/29
Actual recruitment start date
2018-05-22, 1397/03/01
Actual recruitment end date
2019-03-20, 1397/12/29
Trial completion date
2019-03-20, 1397/12/29

Scientific title

The prevalence of antibiotic resistance in pediatrices (3-15 years old) with streptococcal pharyngitis

Public title
The prevalence of antibiotic resistance in pediatrices (3-15 years old) with purulent sore throat
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1- No history of tonsillectomy No antibiotics in the last two weeks Absence of complaints and symptoms of upper respiratory infection (cough, sneezing and runny nose) Justification of the patient or his family and patients' desire to participate in the study
Exclusion criteria:
Age under 3 or over 15 years
Age
From **3 years** old to **15 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **310**
Actual sample size reached: **310**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kashan University of Medical Sciences
Street address
Qutb Ravandi Boulevard
City
kashan
Province
Isfehan
Postal code
87159-81151
Approval date
2018-05-21, 1397/02/31
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1397.004

Health conditions studied

1

Description of health condition studied
Streptococcal pharyngitis
ICD-10 code
J02.0
ICD-10 code description
Streptococcal pharyngitis

Primary outcomes

1

Description
Throat culture
Timepoint
Throat culture at the beginning of the study and After prescribing antibiotics
Method of measurement
Swap and culture dish

Secondary outcomes

1

Description
Antibiogram
Timepoint
After administration of antibiotics in positive culture cases
Method of measurement
Antibiotic disc

Intervention groups

1

Description
Patients with positive culture, ie definite cases of streptococcal pharyngitis; Divided into 4 groups Intervention group 1: (Penicillin group) In this group of patients weighing less than 27 kg one dose of penicillin 6.3.3 muscle ampoule and Patients weighing more than 27 kg one dose of penicillin muscle ampoule 1.2 million units and 48 hours later re-culture and antibiogram were performed to evaluate antibiotic resistance.(Tri-Pen vial 6.3.3 and Benzapen vial 1,200,000 units)
Category
Treatment - Drugs

2

Description
Intervention group2 : azithromycin group In this group, patients treated with suspension or azithromycin tablets with a dose of 12 mg per kg, single daily dose for 5

days.Then re-culture and antibiogram were performed to evaluate antibiotic resistance.(Azithromycin suspension 100 and 200 mg and tablets 250 and 500 mg from Farabi company)

Category

Treatment - Drugs

3

Description

Intervention group3: clindamycin group In this group, patients were treated with clindamycin at a dose of 7 mg per kg per dose, every 8 hours, for 10 days.Then re-culture and antibiogram were performed to evaluate antibiotic resistance.(Clindafarm capsules 150 and 300 mg)

Category

Treatment - Drugs

4

Description

Intervention group4: amoxicilin group In this group, patients were treated with amoxicillin at a dose of 50 mg per kg daily, divided every 8 hours, for 10 days.Then re-culture and antibiogram were performed to evaluate antibiotic resistance.(Amoxicillin suspension 125 and 250 mg and capsules 250 and 500 mg from Farabi company)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Shahid Beheshti Hospital

Full name of responsible person

maryam shammaei zavareh

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Qutb Ravandi Boulevard, Shahid Beheshti Hospital, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

dr maryam shammaei zavareh

Position

Pediatrician

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Non-disclosure of patient information
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