

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The prevalence of antibiotic resistance in peditrices (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

Maryam Shammaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3230 3245

Email address

mary.zavare@yahoo.com

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
Isfahan
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: amoxicillin 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

Street address

Qutb Ravandi Boulevard, Shahid Beheshti Hospital, Kashan

City

kashan

Province

Isfahan

Postal code

87159-81151

Phone

+98 31 5554 0026

Fax

+98 31 5554 8900

Email

mary.zavare@yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

dr davood kheirkhah

Street address

Qutb Ravandi Boulevard

City

kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0021

Email

drkheirkhah@yahoo.com

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

Street address

Qutb Ravandi Boulevard

City

kashan

Province

Isfahan

Postal code

87159-81151

Phone

0098315540026

Email

mary.zavare@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

dr davood kheirkhah

Position

Pediatrician (Assistant Professor)

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Qutb Ravandi Boulevard

City

kashan

Province

Isfahan

Postal code

87159-81151

Phone

+98 31 5554 0026

Email

drkheirkhah@yahoo.com

Person responsible for updating data

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

Street address

Qutb Ravandi Boulevard

City

kashan

Province

Isfahan

Postal code

87159-81151

Phone

+98 31 5554 0026

Email

mary.zavare@yahoo.com

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