Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of Half-Dose Oral Amoxicillin in Reducing Hospitalization Rates for Aspiration Pneumonia in Patients with Neuromuscular Disease and Cerebral Palsy: A Randomized Controlled Trial

Protocol summary

Study aim

The objective of this study is to assess the efficacy of prophylactic half-dose amoxicillin in reducing the frequency of hospitalizations due to aspiration pneumonia in children aged 6 months to 15 years with severe neurological disorders and cerebral palsy, who are under related neurological treatment and present with recurrent respiratory infections and a history of at least one hospitalization due to aspiration pneumonia.

Design

This study is a single-center, randomized, double-blind, placebo-controlled clinical trial with a crossover design, conducted in Tehran Children's Medical Center.

Settings and conduct

The trial is conducted at the Tehran Children's Medical Center, a tertiary care hospital specializing in pediatric care. both the participants (or their caregivers) and the healthcare providers administering the intervention or placebo are blinded. The trial is conducted in two phases over a period of six months.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children aged between 6 months and 15 years. Diagnosis of severe neurological disorders and cerebral palsy. Undergoing related neurological treatment. History of recurrent respiratory infections. Have been hospitalized at least once due to aspiration pneumonia. Exclusion Criteria: Known allergy or intolerance to amoxicillin. Current use of other prophylactic antibiotics for any other condition. Presence of a co-existing severe immunodeficiency. Existence of other severe chronic diseases which may influence the frequency of hospitalizations. Lack of legal guardian or caregiver consent for participation in the trial.

Intervention groups

The intervention in this study is the administration of prophylactic half-dose amoxicillin (25mg/kg body weight daily, orally) for a period of 3 months.

Main outcome variables

frequency of hospitalizations due to aspiration pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221126056619N1**
Registration date: **2023-06-11, 1402/03/21**
Registration timing: **prospective**

Last update: **2023-06-11, 1402/03/21**
Update count: **0**

Registration date

2023-06-11, 1402/03/21

Registrant information

Name

Nazanin Nasri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of Half-Dose Oral Amoxicillin in Reducing Hospitalization Rates for Aspiration Pneumonia in Patients with Neuromuscular Disease and Cerebral Palsy: A Randomized Controlled Trial

Public title
investigation the effective of oral amoxicillin with half the therapeutic dose in reducing the hospitalization rate of patients with neuromuscular disease and cerebral palsy due to aspiration pneumonia during the years 1401-1402
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged between 6 months to 15 years suffering from severe neurological diseases and cerebral palsy undergoing related neurological treatments. Patients who have presented with recurrent respiratory infections and have a previous history of at least one hospitalization due to aspiration pneumonia. Patients who have been evaluated for demographic conditions, socioeconomic level, oral and dental nutrition status, care hygiene, cognitive status, movement and musculoskeletal conditions, and respiratory conditions, including dependence on respiratory devices.
Exclusion criteria:
Patients who do not tolerate the oral antibiotic (Amoxicillin) treatment or show gastrointestinal symptoms will be excluded from the study. Any severe illness or medical condition that, in the opinion of the investigator, might interfere with the patient's participation in the study.
Age
From **6 months** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
a suitable randomization method could be block randomization, which would ensure equal numbers of participants receive either half-dose amoxicillin or a placebo, at any given time. Individual participants would be the unit of randomization, and if necessary, stratified randomization could be used to control for variables like age, disease severity, or sex. A computerized random number generator, in software like Microsoft Excel or SPSS, would be used to create the random allocation sequence. The random sequence, built based on the chosen randomization method, would be used to assign participants to groups in a way that conceals allocation. This could be accomplished using a centralized web-based system which reveals the participant's group only after enrollment is confirmed, hence preventing selection bias. This randomization strategy, if implemented, would convert your study into a randomized controlled trial, enabling direct comparison of the effectiveness of prophylactic half-dose amoxicillin versus a placebo in preventing aspiration pneumonia in your target population.
Blinding (investigator's opinion)
Double blinded
Blinding description
blinding applied to three groups: the participants, the individuals administering the interventions, and the team evaluating the outcomes. Let's go through how this can be achieved for each group: Participants: the patients (or their caregivers) will not be told whether they are receiving the amoxicillin or the placebo. Both the amoxicillin and the placebo will need to look and taste identical, to prevent the participants from guessing their group assignment. Healthcare Providers: Physicians, nurses, physiotherapists, and any other professionals involved in administering the intervention or providing care to participants during the trial will also be blinded. They won't know whether they're administering amoxicillin or placebo to a particular patient. This could be achieved by having a separate team responsible for the packaging and labeling of the intervention (amoxicillin or placebo). The intervention would be delivered in an identical, coded package, and the code would only be broken once the study is completed. Outcome Assessors and Data Collectors: Those who assess the outcomes (for example, frequency of aspiration pneumonia) and those who collect the data will also be blinded to group assignment. They'll only have access to the coded group assignments and won't know which code corresponds to the amoxicillin group and which corresponds to the placebo group. This is important to ensure that their knowledge doesn't influence the assessment of outcomes or data collection.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Children's Medical Center, Dr Gharib St, Keshavarz Blvd, Tehran, Iran
City
tehran
Province
Tehran
Postal code
1419733151

Approval date
2023-06-06, 1402/03/16

Ethics committee reference number
IR.TUMS.CHMC.REC.1402.050

Health conditions studied

1

Description of health condition studied
Aspiration Pneumonia
ICD-10 code
J69
ICD-10 code description
Pneumonitis due to solids and liquids

2

Description of health condition studied
Cerebral Palsy
ICD-10 code
G80
ICD-10 code description
Cerebral palsy

Primary outcomes

1

Description
The primary outcome measure in this study is the reduction in the frequency of hospitalizations due to aspiration pneumonia in the children undergoing prophylactic treatment with half-dose amoxicillin, compared to the period when they are not receiving the antibiotic.

Timepoint
Baseline measurement: This is done before the intervention starts to document the initial frequency of hospitalizations due to aspiration pneumonia.During the intervention phase (first three months): The primary outcome is measured monthly, providing three data points at the end of the 1st, 2nd, and 3rd month after the start of the intervention.Post-intervention phase (following three months): The frequency of hospitalizations due to aspiration pneumonia is monitored for another three months after discontinuation of the intervention. This gives three additional data points, measured at the end of the 4th, 5th, and 6th month from the start of the study.

Method of measurement
Review of Medical Records: The number of hospitalizations each participant has had due to aspiration pneumonia is obtained by reviewing their medical records. This will be done by authorized research personnel who have been trained to accurately extract this information. This method allows for the collection of reliable and accurate data regarding the primary outcome.Patient and Caregiver Reports: In addition to the review of medical records, the caregivers of the patients (or the patients themselves, if appropriate) will be asked about any hospitalizations that have occurred due to aspiration pneumonia. This helps to ensure that all relevant information is captured, even if it might not be reflected in the medical records.

Secondary outcomes

empty

Intervention groups

1

Description
In the first phase of the study, patients within the age group of 6 months to 15 years with severe neurological diseases and cerebral palsy who have a history of at least one episode of hospitalization due to aspiration pneumonia are administered half-dose Amoxicillin (25 mg per kg of body weight) orally, on a daily basis, for three months, in addition to their standard neurological treatment.

Category
Prevention

2

Description
Control group: In the second phase of the study, the same group of patients as in Intervention Group 1 discontinue the use of Amoxicillin for the following three months while continuing with their standard neurological treatment. The outcome (number of hospitalizations due to aspiration pneumonia) during this phase without antibiotic treatment serves as the control for comparison.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Children's Medical Center
Full name of responsible person
seyyed hosein mirlohi
Street address
Children's Medical Center, Dr Gharib St, Keshavarz Blvd, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
seyyed hosein mirlohi
Street address
Children's Medical Center, Dr Gharib St, Keshavarz Blvd, Tehran, Iran
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sh.mirlohi۲۰۰۴@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Nazanin Nasri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

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Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Nazanin Nasri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics

Street address
No 7,center ordibehesht,south makooyi poor,behzadi blvd,zaferaniyeh neighbourhood
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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
This dataset will include all collected de-identified Individual Participant Data (IPD) pertaining to this study. This includes: Baseline demographic information (age, gender, neurological condition specifics, past medical history) Detailed dosage and duration information related to the administration of Amoxicillin. Information regarding standard neurological treatments given alongside the study intervention. Outcome data concerning frequency of hospitalizations due to aspiration pneumonia during both the intervention phase and control phase. Any recorded side effects or adverse events. Please note that all data will be fully anonymized to protect participant privacy, and any sensitive data fields will be carefully managed in compliance with relevant data protection regulations.
When the data will become available and for how long
The data from this clinical trial will become available starting six months after the publication of the study's primary results, anticipated to be around January 2024. These files will remain accessible for a period of five years until December 2028. This window of availability allows for further independent analysis and meta-analysis by interested researchers while maintaining the balance with the need for data freshness and relevancy. Access requests submitted after the end date will be reviewed on a case-by-case basis.
To whom data/document is available
The de-identified individual participant data (IPD) and supporting documents will be shared with qualified researchers worldwide, regardless of their affiliation with academic, non-profit, or for-profit organizations. The primary requirement is that the requesting party must be engaged in health-related research and have a methodologically sound proposal for the use of data. Requests from all eligible parties will be considered to promote widespread data utilization and advance our collective understanding of severe neurological disorders and aspiration pneumonia in children.
Under which criteria data/document could be used
Access to the de-identified individual participant data (IPD) and associated documents will be granted for purposes of scientific research that aligns with public good. Requests for access will be reviewed based on the following criteria: The proposed study must have a clear scientific aim and a sound methodology. The requested data must be necessary to achieve this aim. The requesting researcher or research team must demonstrate adequate expertise and experience to conduct the proposed analysis. The proposed use of data must comply with relevant ethical standards and regulations for data protection and patient privacy. The requester must commit to use the data only for the proposed analysis, to not attempt to identify individual participants, and to securely destroy the data after the completion of the analysis. Requests for data access will be reviewed by a data access committee, composed of members of our research team and independent experts. The committee will assess each request based on the outlined criteria and provide a response within four weeks of the request. If access is granted, data will be shared through a secure data-sharing platform, along with relevant documentation to aid in its interpretation and use.
From where data/document is obtainable
All requests for the de-identified individual participant data (IPD) and accompanying documents should be directed to the study's principal investigator. Interested researchers can submit a written proposal detailing their intended use of the data to the following email address: [sh.mirlohi۲۰۰۴@gmail.com]. Please note that all requests will be acknowledged upon receipt, and you will be updated regarding the status of your request within four weeks.
What processes are involved for a request to access data/document
The process to access these documents or data files is designed to ensure a secure, ethical, and effective use of the data. The steps involved are as follows: Initial Proposal Submission: Interested researchers should first submit a written proposal to the specified email address. This proposal should outline the purpose of the requested data, the specific datasets required, and the proposed statistical analysis method. Proposal Review: Upon receiving a proposal, our research team will review it to ensure that the requested data will be used for valid scientific or medical research. This review process usually takes about 2-4 weeks. Data Use Agreement: If the proposal is approved, the researcher will be asked to sign a data use agreement. This agreement outlines the terms and conditions for using the data, including commitments to maintain participant confidentiality, not

to attempt re-identification, to use the data only for the approved purpose, and to dispose of the data after the agreed period. Data Access: Once the data use agreement is signed and returned, our data management team will prepare the requested datasets. This process may take another 2-4 weeks, depending on the complexity and size of the requested data. Follow-Up: After the data is received, the researchers are expected to comply with periodic progress reports and to share their findings with our team before any publication or public dissemination of results. In total, researchers should anticipate that the entire process, from initial proposal submission to receiving the data, may take up to 2-3 months. We encourage researchers to plan accordingly and appreciate their understanding and patience.

Comments