Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Oral Acyclovir in Treatment of Infectious Mononucleosis in Children, Iran, Gorgan, Taleghani Hospital ,2021; A Double Blind Placebo Controlled Clinical Trial

Protocol summary

Study aim
Reduce the duration of treatment and the severity of the disease

Design
Randomized, superiority, parallel group trial design of 46 patients with blinded outcome assessment.
Randomization with block randomization method,

Settings and conduct
This double-blind clinical trial study was performed on children with infectious mononucleosis admitted to Taleghani Children's Hospital in Gorgan in 2021.

Participants/Inclusion and exclusion criteria
Inclusion criteria: children (1 to 16 years old) who have symptoms of the disease including sore throat, lymphadenopathy and fatigue; symptoms begin within the last 3 days; fever 38 c. Exclusion criteria: no need for hospitalization; underlying diseases such as diabetes and asthma; antiviral and steroid treatment for the past 2 weeks; serum creatinine higher than 1.6.

Intervention groups
Intervention group: Acyclovir 80 mg / kg / 24hr recipients in 4 divided doses for 5 days (acyclovir tablets made by Amin Pharma, Iran). Control group: starch tablet receivers for 5 days just like intervention groups(barij sansei,Iran)

Main outcome variables
Reduce the duration of treatment and the severity of the disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201201049554N1**
Registration date: **2021-02-21, 1399/12/03**
Registration timing: **prospective**
Last update: **2021-02-21, 1399/12/03**
Update count: **0**

Registration date
2021-02-21, 1399/12/03

Registrant information

Name
Abdolmotalleb Mazidi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3222 7720

Email address
dr.mazidi@goums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-05, 1399/12/15

Expected recruitment end date
2021-05-21, 1400/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Oral Acyclovir in Treatment of Infectious Mononucleosis in Children, Iran, Gorgan, Taleghani Hospital ,2021; A Double Blind Placebo Controlled Clinical Trial

Public title
Effectiveness of Oral Acyclovir in Treatment of Infectious Mononucleosis in Children

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children (1 to 16 years old) who have symptoms of the disease including sore throat, lymphadenopathy and fatigue Symptoms begin within the last 3 days fever 38 c
Exclusion criteria:
No need for hospitalization Underlying diseases such as diabetes and asthma Antiviral and steroid treatment for the past 2 weeks serum creatinine higher than 1.6
Age
From **1 year** old to **16 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
We use the block randomization method to randomize subjects into groups that result in equal sample sizes. We use the block size 4. From the following blocks, first select 1 by accident and divide the samples into 2 groups according to the order and fill the blocks A for acyclovir and B placebo
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study is double-blind and the medical examiner resident, medication provider and patients would not know about the type of treatment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Golestan University of Medical Sciences
Street address
Golestan University of Medical Sciences, Gorgan,Shastkola road, Philosophical Higher Education Complex
City
Gorgan
Province
Golestan
Postal code
4934174515
Approval date
2021-01-24, 1399/11/05
Ethics committee reference number
IR.GOUMS.REC.1399.345

Health conditions studied

1

Description of health condition studied
Infectious Mononucleosis
ICD-10 code
B27.10
ICD-10 code description
Cytomegaloviral mononucleosis, without complications

Primary outcomes

1

Description
Reduce the hospitalization duration
Timepoint
The patient's general condition and the presence of respiratory distress will be assessed daily after starting treatment
Method of measurement
Medical assessment and physical examination

2

Description
Reduce severity of disease
Timepoint
The presence of fever, exudative sore throat, respiratory distress, stridor is evaluated daily after starting treatment
Method of measurement
Medical assessment and physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Acyclovir 80 mg / kg / 24hr recipients in 4 divided doses for 5 days (acyclovir tablets made by Amin Pharma, Iran)
Category
Treatment - Drugs

2

Description
Control group: Placebo group (starch placebo product of Barij Essential Company) in 4 divided doses for 5 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Dr. Jabar Parhiz
Street address
Philosophical Higher Education Complex, Shast Kola Road, Gorgan
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3220 2565
Email
drparhiz.jbr@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Honarvar
Street address
Philosophical Higher Education, Shast Kola Road, Gorgan
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3245 1660
Email
info@goums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Abdolmotaleb Mazidi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Golestan University of Medical Sciences, Shast Kola Road, Gorgan
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3220 2565
Email
drmazidimd@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Abdolmotaleb Mazidi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Golestan University of Medical Sciences, Shast Kola Road, Gorgan
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3220 2565

Email
drmazidimd@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Gorgan University of Medical Sciences

Full name of responsible person
Abdolmotaleb Mazidi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
Golestan University of Medical Sciences, Shast Kola Road, Gorgan

City
Gorgan

Province
Golestan

Postal code
4934174515

Phone
+98 17 3220 2565

Email
drmazidimd@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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