

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

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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

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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

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

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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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