Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of high doses of prednisolone and ACTH on the treatments of infants with infantile spasms

Protocol summary

Study aim
Comparison the effects of high doses of prednisolone and ACTH on the treatment of infantile spasms

Design
Clinical trial with control and parallel groups, single blind, and randomized

Settings and conduct
This is a single blind study in which the analyst is unaware of the intervention and treatment groups and the patients referring to Ghaem hospital and clinic in Mashhad will be randomly assigned to 2 groups

Participants/Inclusion and exclusion criteria
Inclusion criteria: all patients with infantile spasm within the age range of 2 to 12 months with abnormal electroencephalography where seizures started at most one month ago with no control over seizures. Exclusion criteria: previous use of corticosteroids or ACTH in any way; brain structural disorder; active infections; history of hypertension and history of heart and kidney diseases.

Intervention groups
Intervention group: patients will be treated with high doses of prednisolone tablets at first with 8 mg/kg in 3 doses with a maximum of 60 mg daily for two weeks and in case of appropriate response, treatment with prednisolon with 6 mg/kg in 3 doses per 8 hours will continue for 5 days and then, 4 mg/kg in 2 doses per 12 hours for another 5 days and next, 2 mg/kg daily for the last 5 days will be prescribed. Control group: patients will receive intramuscular injection of ACTH with dosage of 2 to 3 units/kg daily for 5 days and next prednisolone tablet with dosage of 2 mg/kg daily for 3 weeks and every other day for the rest of the treatment.

Main outcome variables
Investigation of seizure status; electroencephalography 2 weeks after the commencement of the study

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200131046317N1**
Registration date: **2020-02-17, 1398/11/28**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-17, 1398/11/28**
Update count: **0**

Registration date
2020-02-17, 1398/11/28

Registrant information

Name
Javad Akhondian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3841 7451

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akhondianj@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-29, 1398/11/09

Expected recruitment end date
2020-10-30, 1399/08/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of high doses of prednisolone and ACTH on the treatments of infants with infantile spasms

Public title
Comparison of the effects of high doses of prednisolone and ACTH on the treatment of infantile spasms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with infantile spasm within the age range of 2 to 12 month Abnormal Electroencephalography where seizures started a most one month ago with no control over seizures
Exclusion criteria:
Previous use of corticosteroids or ACTH in any way Known metabolic cause Brain structural disorder, active infections, history of hypertension and history of heart and kidney diseases
Age
From **2 months** old to **12 months** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is conducted through table of random numbers available at 'www.randomization.com' website where numbers are placed in sealed envelopes assigning patients to one of the two groups
Blinding (investigator's opinion)
Single blinded
Blinding description
The analyst will be unaware of the intervention and control groups
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2019-12-05, 1398/09/14
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.745

Health conditions studied

1

Description of health condition studied
Infantile spasm
ICD-10 code
G99
ICD-10 code description
Other disorders of nervous system in diseases classified elsewhere

Primary outcomes

1

Description
Seizures status
Timepoint
Two weeks after the commencement of the treatment
Method of measurement
Based on parents' reports

2

Description
Electroencephalography
Timepoint
Before treatment and two weeks after commencement of the treatment
Method of measurement
Conducting electroencephalography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients will be treated with high doses of prednisolone tablets under the brand of Iran Hormone Pharmaceutical Corporation and the trade name of nisopred where at the beginning, the treatment will start with 8 mg/kg in 3 doses with a maximum of 60 mg daily for two weeks and in case of appropriate response (no seizure up to 24 hours), treatment with prednisolon with 6 mg/kg in 3 doses per 8 hours will continue for 5 days and then, 4 mg/kg in 2 doses per 12 hours for another 5 days and next, 2 mg/kg daily for the

last 5 days will be prescribed. In all stages, the maximum dosage is 60 mg daily.

Category

Treatment - Drugs

2

Description

Control group: Intramuscular injection of ACTH under the brand of Iran Hormone Pharmaceutical Corporation and the trade name of synacran with the dosage of 2 to 3 units/kg daily for 5 days and next prednisolone tablet under the brand of Iran Hormone Pharmaceutical Corporation and the trade name of nisopered with dosage of 2 mg/kg daily for 3 weeks and every other day for the rest of the treatment will be prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem hospital

Full name of responsible person
Shima ImanNezhad

Street address
Ghaem hospital, Ahmad Abad Ave.

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Mashhad

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9176699199

Phone
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohsen Tafaghodi

Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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Province
Razavi Khorasan

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Shima Iman Nezhad

Position
Student of sub specialist

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Javad Akhondian

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

Contact
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Shima Iman Nezhad
Position
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Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data can be shared after patients are made unidentifiable.
When the data will become available and for how long
Data can be accessible 6 months after results are published.
To whom data/document is available
Data will be available for researchers in universities and other scientific institutes.
Under which criteria data/document could be used
Carrying out analysis on data is permitted.
From where data/document is obtainable
Data can be accessible through sending an email to the corresponding author.
What processes are involved for a request to access data/document
After sending a request email to the corresponding author, data will be sent in 1 month.
Comments