

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A Comparative of high dose and low dose adrenocorticotrophic hormone (ACTH) therapy for infantile spasm

Protocol summary

Summary

1-Objectives: To determine the effect of treatment with high and low dose of ACTH in patients with infantile spasms in terms of number of seizures, Hospitalization, medications, side effects and short-term prognosis. 2- design: The study is single center. sample size 30 infants with infantile spasms, they were divided into two groups with high and low dose of ACTH therapy. Randomized single blind study. 3- setting and conduct: After the treatment of patients during 18 months we follow up of the objectives of the study. 4- participants: Infant with infantile spasm with consent of parent to start treatment . 5-Intervention: Ampul ACTH 10 mg , 0/1 mg and 0/25 mg injection 6-Primary and secondary outcome variables: Number of seizures, Hospitalization, medications, side effects and short-term prognosis, blood glucose and blood pressure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060110634N2**

Registration date: **2016-02-09, 1394/11/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-09, 1394/11/20

Registrant information

Name

Afshin Fayazi

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

afshin_fay@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamedan University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative of high dose and low dose adrenocorticotrophic hormone (ACTH) therapy for infantile spasm

Public title

A Comparative of high dose and low dose adrenocorticotrophic hormone (ACTH) therapy for infantile spasm

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: infant with infantile spasm exclusion criteria: 1-cancel from participation in research 2-Lack of consent to start therapy

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Randomization was performed by blocking .

Secondary Ids

1

Registry name

N/A

Secondary trial Id

N/A

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of hamedan University of Medical Sciences

Street address

Univercity of medical sciences, Pajoohesh crossroad, Hamedan city, Iran

City

Hamedan

Postal code

Approval date

2015-01-17, 1393/10/27

Ethics committee reference number

16/35/9/5432

Health conditions studied

1

Description of health condition studied

Infantile spasm

ICD-10 code

G40.4

ICD-10 code description

Other generalized epilepsy and epileptic syndromes

Primary outcomes

1

Description

Count of seizure

Timepoint

6 months later intervention

Method of measurement

Clinical scale

2

Description

Hospitalization duration

Timepoint

6 months later intervention

Method of measurement

day

3

Description

Demands of other drugs

Timepoint

6 months later intervention

Method of measurement

Clinical scale

4

Description

Prognosis

Timepoint

6 months after intervention

Method of measurement

Clinical veiw

Secondary outcomes

1

Description

Hypoglycemia

Timepoint

6 months after intervention

Method of measurement

glocometry

2

Description

Blood pressure

Timepoint

6 months after intervention

Method of measurement

Manometr

Intervention groups

1

Description

Intervention group: ACTH injection Ampul 10 mg / 0/25 mg/ novartis products/ According to PRrotocol of study for 6 months.

Category

Treatment - Drugs

2

Description

Control group: ACTH Ampul injection 10 mg/ 0/1 mg According to Protocol of study for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Samira Mokhtari

Street address

Motahharo bulvar, Resalat sequire,Hamedan city, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Hamedan Univercity of Medical Sciences

Full name of responsible person

Mohammad taghi Goodarzi

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Hamedan Univercity of Medical Sciences, Pajooresh crossroads, Hamedan, Iran

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Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Hamedan Univercity of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Samira Mokhtari

Position

Pediatric Rezident

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty