

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of effect of DHA drop in development progression of gross motor and head circumference in children between 6 month and one years old Has a head growth disorder referred to Hazrat Masoumeh Hospital in Qom in 2022-2023

Protocol summary

Study aim

Investigating the effect of DHA on the development of children between 6 months and one year

Design

Clinical trial, randomization with R software. Randomized to one of two intervention or placebo groups. in a double-blind manner The number of samples is 60 people. Based on a study in Urmia.

Settings and conduct

Two groups of children. Between 6 months and 1 year in Masoumeh hospital in Qom with developmental disorder and small head circumference. For 6 months, one group was given only vitamin AD drops and the second group was given AD and DHA drops in the amount of 40 mg. The therapist and the patient do not know the drops.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children, both boys and girls, between the ages of 6 months and one year, with small head circumference according to age and developmental disorder Exit criteria: Allergy symptoms in children Intolerance of drops Lack of interest of parents to continue studying Premature babies, cerebral palsy, metabolic, twins or multiples, history of head trauma, history of brain infection

Intervention groups

The main group received AD and DHA drops in the amount of 40 mg and the control group only received AD vitamin drops. double blind The results before and after the start of the intervention are extracted and compared from the checklist of the questionnaire. The results of the blood test and the head circumference are checked before and after the intervention. Bar.

Main outcome variables

the degree of evolution in gross movements; growth around the head; blood HDL level; blood LDL level; Blood TG level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220920056000N1**

Registration date: **2023-11-11, 1402/08/20**

Registration timing: **prospective**

Last update: **2023-11-11, 1402/08/20**

Update count: **0**

Registration date

2023-11-11, 1402/08/20

Registrant information

Name

elham farasat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3162 5224

Email address

farasat_med@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-26, 1402/10/05

Expected recruitment end date

2024-03-24, 1403/01/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of DHA drop in development progression of gross motor and head circumference in children between 6 month and one years old Has a head growth disorder referred to Hazrat Masoumeh Hospital in Qom in 2022-2023

Public title

Evaluation of effect of DHA drop in development progression of gross motor and head circumference in children between 6 month and one years old Has a head growth disorder referred to Hazrat Masoumeh Hospital in Qom in 2022-2023

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children, both boys and girls, between the ages of 6 months and 1 year, who are referred to Hazrat Masoumeh Hospital in Qom with small head circumference according to their age and developmental disorder.

Exclusion criteria:

Allergy symptoms in children Intolerance of drops and vomiting Lack of interest of parents to continue studying Premature babies Cerebral Palsy Metabolic disorder Two or more twins History of head trauma History of brain infection

Age

From **6 months** old to **1 year** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization pattern: block - randomization unit: individual - randomization tool: R software - in a two-way blind way

Blinding (investigator's opinion)

Double blinded

Blinding description

After obtaining a written consent, medicine is given for 6 months, one group is given only vitamin AD drops and the second group is given AD and DHA drops in the amount of 40 mg. The appearance of the drops is the same and neither the therapist nor the patient can distinguish the type of drops

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

Pediatric Clinical Research Development Unit, Hazrat Masoumeh Educational and Therapeutic Center, Imam Khomeini Street after Shahid Zainuddin Square, Qom, Iran.

City

Qom

Province

Ghous

Postal code

3713649373

Approval date

2022-08-29, 1401/06/07

Ethics committee reference number

IR.MUQ.REC.1401.119

Health conditions studied

1

Description of health condition studied

developmental disorder

ICD-10 code

G93.9

ICD-10 code description

Disorder of brain, unspecified

Primary outcomes

1

Description

Size around the head of children 6 months to one year

Timepoint

Once every 2 months until 6 months, i.e. 4 times (beginning of birth, 2 months, 4 months, and 6 months)

Method of measurement

Measure and compare with graph

2

Description

Development of gross movements of children from 6 months to one year

Timepoint

Once every 2 months until 6 months, i.e. 4 times (beginning of birth, 2 months, 4 months, and 6 months)

Method of measurement

Evolution Questionnaire

Secondary outcomes

1

Description

Ability to acquire movement skills

Timepoint

Once every 2 months until 6 months, i.e. 4 times (beginning of birth, 2 months, 4 months, and 6 months)

Method of measurement

Evolution Questionnaire

Intervention groups

1

Description

Intervention group: Intervention group: children, both boys and girls (whose number will be equal in both groups) between the ages of 6 months and 1 year, who are referred to Hazrat Masoumeh Hospital in Qom due to developmental disorders and small head circumference. DHA is given to patients in the amount of 40 mg

Category

Treatment - Drugs

2

Description

Control group: children, both boys and girls (whose number will be the same in both groups) between the ages of 6 months and 1 year, who are referred to Hazrat Masoumeh Hospital in Qom due to developmental disorders and small head circumference after obtaining A written consent is given for 6 months of medication and they only receive vitamin AD drops

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Masoumeh Hospital in Qom

Full name of responsible person

Dr. Mohsen Mullahammadi

Street address

Qom. Imam Khomeini Street - after Shahid Zainuddin Square - Hazrat Masoumeh Hospital

City

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3719815539

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Mohsen Mullahammadi

Street address

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Grant name

Vice President of Research, Qom University of Medical Sciences

Grant code / Reference number

2661

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

Yes

Title of funding source

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Mohsen Mullahammadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Position

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Latest degree

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Fax**Email**

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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

No - There is not 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

A part of the data such as the information related to the main outcome or the like can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For use in similar research projects

From where data/document is obtainable

Elham farasat - Hazrat Masoumeh Hospital, Qom

What processes are involved for a request to access data/document

Request from the vice president of research

Comments