

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of hydrotherapy on the motor development and spasm scores of the cerebral palsy infants

Protocol summary

Study aim

Determine the effect of hydrotherapy on motor evolution and spasm in infants with cerebral palsy.

Design

A clinical trial is a randomized, two-group randomized, pre-test, and post-test. The selection of units of study is available in (easy) among children with cerebral palsy eligible who have criteria for entry to study. Then, The research units were randomly allocated and homogenized into two groups of intervention (receiving hydrotherapy) and control.

Settings and conduct

Perform intervention: The patients will work under the supervision of a researcher and physiotherapist, who will be held for 8 weeks a weekly 3 times in 1-hour sessions, 15 minutes for maternity and dressing for one or two days. Due to administrative conflicts in the morning shift and the relative relaxation of the hospital in the shift in the era of intervention in the shift of the evening. Measurement of the second stage: After the intervention in the intervention group (the eighth week after the intervention), the second stage will measure the criteria for fine motor development and the score for spasm. At this stage, as in the first stage, the evolutionary clinic of the Ghayeg hospital Billy and Ashworth will be used to measure the evolutionary criteria in the sensory-motor field and the spasm scores

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Iranian citizenship and resident of Mashhad. 2) Diagnosis of cerebral palsy for infant is confirmed by the relevant physician. 3) The age of the infant is between 1 and 10 months. Exit criteria: 1) The primary caregiver of the child is not willing to cooperate.

Intervention groups

Infants with cerebral palsy with hydrated intervention

Main outcome variables

Main variables include spasm scores of the upper and lower extremities, and the elevated and gross motor development of infants with cerebral palsy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180427039440N1**

Registration date: **2019-01-17, 1397/10/27**

Registration timing: **retrospective**

Last update: **2019-01-17, 1397/10/27**

Update count: **0**

Registration date

2019-01-17, 1397/10/27

Registrant information

Name

zainab razmyar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-01-26, 1395/11/07

Expected recruitment end date

2017-01-26, 1395/11/07

Actual recruitment start date

2017-01-26, 1395/11/07

Actual recruitment end date

2018-01-27, 1396/11/07

Trial completion date

2019-01-09, 1397/10/19

Scientific title

Effects of hydrotherapy on the motor development and spasm scores of the cerebral palsy infants	
Public title	Effects of hydrotherapy for cerebral palsy
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Diagnosis of cerebral palsy for the infant will be confirmed by the relevant physician. The age of the infant is between 1 and 10 months. Parents have a tendency to participate in the study. According to a physician's diagnosis, with cerebral palsy, there is no physical illness or disorder in other systems of the body, such as any kidney and digestive problems and diabetes. No malnutrition. Exclusion criteria: The child's primary caregiver does not want to cooperate. The infant is admitted or required to undergo surgery. During the intervention, diagnose any disease that affects the development process by the doctor for infants. The infant dies during the intervention.
Age	From 1 month old to 10 months old
Gender	Both
Phase	N/A
Groups that have been masked	• Participant • Data analyser
Sample size	Target sample size: 30 Actual sample size reached: 30
Randomization (investigator's opinion)	Randomized
Randomization description	Translate Turn off instant translation 980/5000 Selection of available research units is easy for children suffering from cerebral palsy who have criteria for entering the study. Subsequently, the units were randomly assigned and homogenized into two groups of intervention (receiving hydrotherapy) and dividing control They must be homogeneous in terms of gender and age before intervention. Before the sampling begins, by assigning either a pair or a person to a control or intervention group, the random numbers are sequentially numbered n (the sample size is a total of two The group is selected based on the number of pairs or individuals. The sequence of children selected by group Control and intervention. For example, if the individual numbers are assigned to the control group and the pair numbers to the intervention group, then the sequence of the numbers selected from the random number table is 8.5.1.4.2.1-6.0.7.7 The allocation of children to The two groups will be based on the sequence of referrals: intervention "control" intervention control "intervention" control "intervention" none "control. Choosing this random allocation method is due to the allocation of resources before the study begins, and no factor affects
	it during the research.
Blinding (investigator's opinion)	Double blinded
Blinding description	Given the random selection of participants and their insertion in the control and intervention group and the use of code instead of the name for data analysis
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	The Ethics Committee of Mashhad University of Medical Sciences
Street address	Faculty of Nursing University Street, Crossroad of the Ph.D.
City	Mashhad
Province	Razavi Khorasan
Postal code	9138735499
Approval date	2017-01-21, 1395/11/02
Ethics committee reference number	IR.MUMS.REC.1395.509
Health conditions studied	
<u>1</u>	
Description of health condition studied	Cerebral palsy
ICD-10 code	G80
ICD-10 code description	Cerebral palsy
Primary outcomes	
<u>1</u>	
Description	Motor Development and Spasm of the infants
Timepoint	Before and after the intervention
Method of measurement	Billy and Ashworth tools

Secondary outcomes

1

Description

Fine motor development, Gross motor development and spasm the Infanti

Timepoint

Before and after the intervention

Method of measurement

Billy and Ashworth tools

Intervention groups

1

Description

In the intervention group, the patients will be under the supervision of a researcher and physiotherapist, who will be held for 8 weeks a weekly 3 times in 1-hour sessions, 15 minutes for maternity leave and alternate dresses on individual or coupled days. will be. Due to administrative conflicts in the morning shift and the relative relaxation of the hospital in the shift in the era of intervention in the shift of the evening. Measurement of the second stage: After the intervention in the intervention group (the eighth week after the intervention), the second stage will measure the criteria for fine motor development and the score for spasticity, which is similar to the first stage in the evolutionary clinic of Ghayegh Hospital Billy and Ashworth evolutionary tools will be used to measure the evolutionary criteria in the sensory-motor field and the spasm score. The control group will be evaluated without any intervention at the beginning and end of the work.

Category

Rehabilitation

2

Description

Control group: In the control group, without any intervention, will be evaluated only at the beginning of the work and the end (end of the two months).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad, Hospital Ghaem

Full name of responsible person

Zainab Razmyar

Street address

Ahmad Abad Ave, Dr. Shariati Square (Taghi Abad),

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Said eslami

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University of Mashhad, Faculty of Nursing and Midwifery, Ibn Sina St., Ph.D.

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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

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

Zainab Razmyar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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