Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

comparison between Rood inhibitory approach and Bobath Reflex inhibiting pattern to improve Gross motor function and reduce spasticity in hemiplegic children of encephalitis

Protocol summary

Study aim

This study will be conducted with an aim of comparing the effects of Rood (Inhibitory) approach and Bobath (Reflex Inhibiting pattern) to reduce spasticity and improve Gross motor Functional Movements in Hemiplegic Children of Encephalitis.

Design

Randomized clinical design

Settings and conduct

1)children hospital faisalabad 2)Gernal hospital Ghulam Muhammada bad faisalbad

Participants/Inclusion and exclusion criteria

N=22 (through epitool, sample size to estimate a simple proportion, apparent prevalence) Patients who agree to give consent will be screened according to set inclusion and exclusion criteria. Patients who meet the eligibility criteria will be enrolled in the study. Patients recruited in the study will be randomly allocated into treatment A (n=11) and treatment B (n=11) groups. Inclusion Criteria: 1. Both gender 2. Hemiplegic Spastic Encephalitis Children 3. Age should be between 2 year to 15 years 4. Spasticity of grade 1 to 3 through Modified Ashworth Scale 5. Chronic Encephalitis children 6. Written Informed Consent. Exclusion Criteria: 1. Spasticity because of any other disease e.g. CP and stroke etc 2. Children having fits and tremors and any red flag sign 3. Children taking any other physical therapy treatment during this study 4. Severe Mental Retardation, Contractures, Decrease Tone 5. Tumor, fractures and any other severe infections 6. Red flag signs that may indicate cauda equina syndrome, such as bladder and bowel Dysfunction and saddle anesthesia 7. History of spinal surgery

Intervention groups

Group 1:Rood inhibitory approach Group 2:Bobath reflex inhibiting pattern

Main outcome variables

Primary outcome measures:Gross Motor functional scale
Secondary outcome measures:Modified Ashworth scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210805052088N1**
Registration date: **2021-08-15, 1400/05/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-15, 1400/05/24**
Update count: **0**

Registration date

2021-08-15, 1400/05/24

Registrant information

Name

NOOr-UL-AIN NOOR-UL-AIN

Name of organization / entity

The university of faisalabad

Country

Pakistan

Phone

+92 41 8502460

Email address

noorulainjerry@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-15, 1400/03/25

Expected recruitment end date

2021-10-15, 1400/07/23

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
comparison between Rood inhibitory approach and Bobath Reflex inhibiting pattern to improve Gross motor function and reduce spasticity in hemiplegic children of encephalitis

Public title
comparison between Rood inhibitory approach and Bobath Reflex inhibiting pattern to improve Gross motor function and reduce spasticity in hemiplegic children of encephalitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Both gender Hemiplegic Spastic Encephalitis Children Age should be between 2 year to 15 years Spasticity of grade 1 to 3 through Modified Ashworth Scale Written Informed Consent. Chronic Encephalitis children
Exclusion criteria:
Spasticity because of any other disease e.g. CP and stroke etc Children having fits and tremors and any red flag sign Children taking any other physical therapy treatment during this study Severe Mental Retardation, Contractures, Decrease Tone Tumor, fractures and any other severe infections Red flag signs that may indicate cauda equina syndrome, such as bladder and bowel Dysfunction and saddle anesthesia History of spinal surgery
Age
From **5 years** old to **15 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **15**
In this study have two groups so total sample size is 30 and in each group have 15 sample size
Randomization (investigator's opinion)
Randomized
Randomization description
Non-probability purposive sampling technique will be utilized to collect sample and the sample will be allocated to treatment group 1 and 2 by using lottery method.Screening of population will be done by using, selected inclusion and exclusion criteria.Lottery method basically is a chit and draw method during allocation make the chits and than said the patients that please collect any one chit than enrolled the patient in respective group.In a chit-pull system, a number of chits is first placed in a container (often a bag or cup). ... In the course of the game, chits are drawn randomly out of this container, triggering certain game effects. This is essentially just another way of producing random results.Patients who met the eligibility criteria will be enrolled in the study.During randomization patients fully blinded than allocate the patients into treatment group 1(Rood inhibitory approach) and treatment group 2(Bobath reflex inhibiting pattern).
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients will be kept blind through allocation concealment to treatment groups.Patients will be unaware of their respective group treatment plans.Patients who met the eligibility criteria will be enrolled in the study.During randomization patients fully blinded than allocate the patients into treatment group 1(Rood inhibitory approach) and treatment group 2(Bobath reflex inhibiting pattern).Basically blinding in research prevent biasness in the study.Patients will be fully unknown about the allocation procedure because used lottery method for allocation of the patients.
Placebo
Not used
Assignment
Parallel
Other design features
Randomized clinical design

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of the university of faisalabad
Street address
Sargodha Rd,University Town,Faisalabad,Punjab 38000
City
Faisalabad
Postal code
38000
Approval date
2021-05-17, 1400/02/27
Ethics committee reference number
TUF/DR/MSPP/295

Health conditions studied

1

Description of health condition studied
Encephalitis is defined as inflamation of brain caused by any viral and bacterial infection but in different researches cause of encephalitis is unknown due to encephalitis patients present with the symptoms of fever,vomiting,headach,spasticity,muscle weakness etc.

ICD-10 code
G04.90
ICD-10 code description
Encephalitis and encephalomyelitis, unspecified

Primary outcomes

1

Description
Gross motor functional scale will use to measure the Gross motor functions and it is a primary outcome measure scale
Timepoint
two times reading will be measure before treatment and after the treatment session in last follow up
Method of measurement
Gross motor functional scale will be utilized to asses the gross motor functional movements

Secondary outcomes

1

Description
Secondary outcome measure of this study will be Modified Ashworth scale.Modified ashworth scale will be used to measure the spasticity
Timepoint
Reading will be measure before treatment session and after 1st follow up,2nd follow up,3rd follow up,4th follow up and in last follow up each reading will be taken after 15 days of treatment in alternative days
Method of measurement
Modified Ashworth scale will be used to measure the spasticity

Intervention groups

1

Description
Intervention group 1:Rood Inhibitory Approach will be receive of group 1 in alternatives days for 4 month duration after the approval of synopsis.•After allocation to treatment Group A and B, level of spasticity will be recorded using modified Ashworth Scale.•GMFM-88 and GMFM-66 scale will also be used to record the improvement of Gross Motor Functional Movements.•Measurement will also be recorded pretreatment.•First reading will be taken on baseline before treatment session•Each reading was taken after the treatment session of 15 days •Data will be collected before treatment and after 2, 4 and 6 weeks of intervention.•Infrared: On baseline for 15 min.•Rood (Inhibitory): Group 1 will be receiving Rolling, Shaking, Slow joint compression, Maintain stretch for 30 mints in alternative days. .Rood inhibitory approach basically is generally accepted.This approach is used to homogenize the muscle tone,correcting the body postures,positioning and improve gross motor functions. Basically its a stretching and specialized method of handling.
Category
Rehabilitation

2

Description
Intervention group 2: Bobath reflex inhibiting patterns technique will be apply in group 2 patients in alternatives days for 4 month duration after the approval of synopsis.•After allocation to treatment Group A and B, level of spasticity will recorded using modified Ashworth Scale.•GMFM-88 and GMFM-66 scale will also be used to record the improvement of Gross Motor Functional Movements.•Measurement will also be recorded pretreatment.•First reading will taken on baseline before treatment session•Each reading will taken after the treatment session of 15 days• Data will be collected before treatment and after 2, 4 and 6 weeks of intervention.Group 2 will be received infrared on baseline for 15 minutes and bobath reflex inhibiting pattern in which traction and light joint compression will be receive for 30 minutes in alternative days. Bobath reflex inhibiting pattern and posture also called tone influencing pattern and postures includes spasticity inhibiting position and postures so the person can move his body parts by his/her on wil. This make the person independent in his daily activities.When the stimulation is given in inhibitory postures than the chance in increase spasticity decrease rapidly.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Children Hospital Faisalabad
Full name of responsible person
Noor-ul-ain
Street address
Jhang Road,GC university,New campus Faisalabad Punjab
City
FAISALABAD
Postal code
38000
Phone
+92 41 9203065
Email
childcare.institute.fais@alabad

2

Recruitment center
Name of recruitment center
Children Hospital Faisalabad
Full name of responsible person
Noor-ul-ain
Street address

Jhang Road,GC university,New Campus Faisalabad Punjab

City
FAISALABAD

Postal code
38000

Phone
+92 41 2551301

Email
Dr.faisl87@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Faisalabad

Full name of responsible person
Dr.Sidra Majeed;PT

Street address
Sargodha Rd,University Town,Faisalabad,Punjab 38000

City
FAISALABAD

Postal code
38000

Phone
+92 41 8868326

Email
info@tuf.edu.pk

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Self Financed

Proportion provided by this source
100

Public or private sector
Private

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
The University of Faisalabad

Full name of responsible person
Noor-ul-ain

Position
Medical student

Latest degree
Medical doctor

Other areas of specialty/work
Physiotherapy

Street address
Kamalia Road banglaw chowk mamunkanjan faisalabad

City
Faisalabad

Province
PUNJAB

Postal code
38000

Phone
+92 41 8502460

Email
noorulainjerry@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
The University of Faisalabad

Full name of responsible person
Noor-ul-ain

Position
Physiotherapist

Latest degree
Medical doctor

Other areas of specialty/work
Physiotherapy

Street address
Kamalia road banglaw chowk mamunkanjan faisalabad

City
Faisalabad

Province
Punjab

Postal code
38000

Phone
+92 41 8502460

Email
noorulainjerry@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
The University of Faisalabad

Full name of responsible person
Noor-ul-ain

Position
Physiotherapist

Latest degree
Medical doctor

Other areas of specialty/work
Physiotherapy

Street address
Kamalia Road Banglaw chawk mamunkanjan Faisalabad

City
Faisalabad

Province

Punjab

Postal code

38000

Phone

+92 41 8502460

Email

noorulainjerry@yahoo.com

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable