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Evaluation of the effectiveness of physical therapy for people with infantile cerebral palsy using the KRISAF robot assistant

Submission date
10/02/2025

Recruitment status
No longer recruiting

Registration date
26/02/2025

Overall study status
Ongoing

Last Edited
06/06/2025

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This is an evaluation of the effectiveness of physical therapy for people with cerebral palsy using the KRISAF assistant robot. Infantile cerebral palsy (CP) is a condition in which a child's muscles and movements are disrupted. This makes it difficult for children to walk, run, stand, and perform other movements. They use physical therapy to improve their condition but this requires special devices. One of these devices is the KRISAF robot assistant. KRISAF helps children perform exercises that they would not be able to do on their own. It supports their body as they move and makes sure they do everything right. To assess the effectiveness of this method, a special scale is used. This helps measure how much the child's motor skills have improved after using a device KRISAF. The higher the score on the scale, the better the child copes with the child's movements. The results show that KRISAF classes can help children with cerebral palsy improve their motor skills. A pilot study was conducted in the medical center of the city of Yekaterinburg, which showed the effectiveness of using the robotic complex. It was decided to repeat this study in several health centers. The aim of the study is to prove the effectiveness of rehabilitation using a robotic complex, which can make children's lives more comfortable, active and independent.

Who can participate?
Children 6-12 years of age with cerebral palsy

What does the study involve?
Participants are randomly allocated to one of two groups, one of which will receive standard treatment and the other standard treatment
including classes at the Krisaf complex.

What are the possible benefits and risks of participating?
The main advantage of the study is the new technology implemented in the Krisaf robotics complex. This complex helps in maintaining and restoring the range of motion in the joints,

normalizing muscle tone and restoring proper execution of body movements. The technology has minimal risks, such as discomfort during sports. If you feel uncomfortable, you can interrupt the session.

Where is the study run from?
Aspect Medical (Russia)

When is the study starting and how long is it expected to run for?
October 2024 to October 2025

Who is funding the study?
Aspect Medical (Russia)

Who is the main contact?
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Contact information

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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of the effectiveness of locomotor therapy in a supportless state using the robot assistive complex KRISAF in patients with cerebral palsy based on the GMFM 66 scale

Acronym
KRISAF

Study objectives
Randomized controlled multicenter study of the effectiveness and safety of a new method of rehabilitation therapy for motor disorders in patients with cerebral palsy with spastic diplegia using a robotic complex for locomotor therapy in an unsupported state

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/12/2024, Committee on Ethics and Deontology of the healthcare institution "Minsk city center for medical rehabilitation of children with Neuropsychiatric diseases" (St Uralskaya 5, Minsk, 220004, Belarus; +375 (17)239-59-12; firststep@cu.bc.by), ref: 2

Study design
Randomized controlled interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cerebral palsy

Interventions
Participants diagnosed with CP with spastic diplegia classified as Gross Motor Function Classification Scale (GMFCS) Levels I-V will be recruited and divided equally into two groups (G1 and G2). Randomization will be performed using the envelope method. The first group (G1) will receive rehabilitation at the complex for locomotor therapy "Krisaf", 8-10 sessions including swimming, jumping, crawling, walking for 5-7 minutes, and jumping-assisted mode for 3-5 minutes. There are only 10 sessions, an average of 30 minutes each. Standard methods of rehabilitation.

Control group (G2): Standard rehabilitation methods. Standard complex of rehabilitation including kinesiotherapy and mechanotherapy.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Robot assistive complex Krisaf

Primary outcome measure
Functional state and motor function measured using the Tardieu scale and Gross Motor Function Measure 66 (GMFM-66) on the 1st day and the 10th day of classes

Secondary outcome measures
Neurological examination on the 1st day and the 10th day of classes

Overall study start date
22/10/2024

Completion date
22/10/2025

Eligibility

Key inclusion criteria
1. Patients with a verified diagnosis of cerebral palsy (spastic forms of cerebral palsy, diplegia and quadriplegia)
2. Aged 6-12 years
3. GMFCS level 1-4

4. The presence of communicative contact with the child (Communication Function Classification System [CFCS] 1-3)
5. Voluntary consent to conduct the study

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
120

Total final enrolment
120

Key exclusion criteria
1. Acute inflammatory diseases
2. Somatic pathology in the stage of decompensation
3. Severe orthopedic disorders (hip dislocation)
4. Lack of communication contact with the child
5. Epilepsy
6. Lack of voluntary consent

Date of first enrolment
06/01/2025

Date of final enrolment
06/04/2025

Locations

Countries of recruitment
Belarus

Russian Federation

Study participating centre
State Institution "Minsk City Center for Social Services for Families and Children"
St Uralskaya 5

Minsk
Belarus
220004

Study participating centre
Multiprofile Clinical Medical Center "Bonum"
St Bardina 4a
Ekaterinburg
Russian Federation
620000

Study participating centre
State Educational Institution TO DLRC "Nadezhda"
Tumen
Russian Federation
223054

Sponsor information

Organisation
Aspect Medical

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Aspect Medical Systems

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Ireland

Results and Publications

Publication and dissemination plan
Publishing results in a peer-reviewed journal

Intention to publish date
05/05/2025

Individual participant data (IPD) sharing plan
The dataset generated and analysed during the current will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	CRF in Russan		06/06/2025	No	No