

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

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| Submission date 10/02/2025 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 26/02/2025 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 06/06/2025 | Condition category Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input checked="" type="checkbox"/> 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?
Tatyana S. Poltavskaya, tysayny@yandex.ru

Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Safety, Efficacy

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

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Robot assistive complex Krisaf

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

12 years

Sex

All

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

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

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 Russian | | 06/06/2025 | No | No |