

Trial Description

Title

Analysis of the predictability of individual DXA-parameter and the proposed diagnosis algorithm regarding the risk of fracture amongst the participants of the therapeutical concept "Auf die Beine" ("walking again").

Trial Acronym

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URL of the trial

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Brief Summary in Lay Language

In this questionnaire study we are going to analyze the predictability of individual DXA-parameters (DXA = dual-xray-absorptiometry = a way to determine bone density using xray technology) and the proposed diagnosis algorithm regarding the risk of fracture of children and juveniles with cerebral palsy (a movement disorder, which cause is in a young age brain damage). Both values are going to be compared to proof if the developed algorithm is a better prediction of the risk of fracture than individual DXA-parameters. If so, it would allow a finer and better monitoring of individual adapted preventive measures.

The collective group that receives the questionnaire is put together of the participants of the therapeutical program "Auf die Beine". This particular program is a rehab program for children and juveniles that suffer mobility/agility problems (age 3-25). After 13 days of intensive physiotherapeutical training (the patients stay in the centre during that time) in the rehab centre in Cologne the patients will be send home for a follow up training with their parents using vibration supported physiotherapy ("Galileo Training").

All together the training at home takes 6 months, after 3 months of this training there is again a 6 day stay in the centre in Cologne. The aim of this concept is an improvement of the motorical/physical abilities and a self-sufficient/independent locomotion of the children and juveniles.

We will ask the patients and their legal guardians for the agreement to use already existing data - participation is optional and the agreement or disagreement is not linked to any consequences towards the training or treatment.

Brief Summary in Scientific Language

In accordance to the questionnaire study and the follow up assessment of the received data of the fracture protocol we are trying to find correlation, that might help us to detect with better sensitivity a higher risk of fractures amongst children that suffer CP (cerebral palsy).

The predictability of the algorithm that has been developed by our work group is being compared with the existing methods/measures of prediction.



If it is possible to narrow down the subgroup of children with cp, that suffer repetitive fractures we would have the chance to start individually adapted preventive measures (such as intensive standing training e.g.) to avoid further fractures.

The protocols will be created and assessed by a doctoral candidate (medical student in university of cologne) chaperoned by doctors of the Uni Reha. The envelopes for the fracture protocols will be already stamped and addressed to the Uni Reha (our centre). That measure should even out the way to participate, also the protocol is written and created easily so that it should not take too much time. Participation or non-participation is not linked to any advantage or disadvantage linked to treatment or training.

The fracture protocols are being assessed with descriptive statistic. We use pseudonymization to secure the data. The questionnaire, the names and all medical details will not be given to a third party. The collective group of patients for the questionnaire study is already existing and contains children in the age range between 8-19. The results of their DXA-measurements are present. Consent of legal guardian(s) is mandatory.

Do you plan to share individual participant data with other researchers?

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00012475**
- Date of Registration in DRKS: **2017/06/26**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **17-085 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **G80 - Cerebral palsy**



Interventions/Observational Groups

- **Arm 1: Monitoring group: Children with cerebral palsy will be asked through and by a questionnaire with a sketch of a skeleton where and when they suffered fractures; also very important after what kind of trauma (adequate / inadequate)**
The results of the questionnaire will be compared with the calculated results (by an algorithm) to find out if there is a comparable similarity: If the results are comparable the predictability of the algorithm is proofed.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

In this questionnaire study we are going to analyze the predictability of individual DXA-parameters and the proposed diagnosis algorithm regarding the risk of fracture of children and juveniles. Both values are going to be compared to proof if the developed algorithm is a better prediction of the risk of fracture than individual DXA-parameters. If so, it would allow a finer and better monitoring of individual adapted preventive measures.

Secondary Outcome

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Countries of recruitment

- **DE Germany**

Locations of Recruitment



- University Medical Center **Uni Kinder Reha - Queen Rania , Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/09/15**
- Target Sample Size: **297**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **8 Years**
- Maximum Age: **19 Years**

Additional Inclusion Criteria

- **clinical diagnosis: Cerebral palsy**
- **patient age between 8-19 years of age**
- **participation at the training concept „Auf die Beine“**
- **height: 120-180 cm**
- **Lean body mass: 15-65 kg**
- **caucasian**
- **written consent by at least one legal guardian**
- **written consent by the patient (if the patient is able to do so**
- **filled out fracture protocol by the legal guardian of the patient**

Exclusion criteria

- **patients <8 and >19 years of age**
- **missing written consent of legal guardian**
- **therapy with growing hormones or with corticosteroids**
- **inhibition in the development and growth due to genetical syndromes or chronic heart- or kidney illness/issues**

Addresses

- **Primary Sponsor**

**UniReha GmbH Rehabilitation für Kinder und Jugendliche
Lindenburger Allee 44
50931 Köln
Germany**



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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Enrolling by invitation**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.