

Trial Description

Title

Spastic Equinus - Comparison between the effects of various ankle foot orthosis concepts

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Spastic equinus is one of the most common problems in children with cerebral palsy. The calf muscle is shortened and weak which impair walking and results in structured deformities without treatment. Currently immobilization of the stretched calf using braces is a popular treatment of non-rigid equinus. The goal is to improve the range of motion of the ankle through elongation of the muscle-tendon unit.

Various concepts for bracing include daytime use and/or wearing time at night. To our best knowledge, the effect of daytime use in addition to braces during night has not been investigated. This could lead to a considerable impact of the compliance of the wearing time of braces and of the dynamic stress of the leg. The goal of this longitudinal study is to investigate the effect of orthotic concepts for spastic equinus on gait, muscle morphology, power generation and passive stiffness of the plantar flexors. This study will include a comparison between knee-ankle-foot-orthoses during night and knee-ankle-foot-orthoses during night with additionally daytime use. Eighty-six children (n=43 each group) with cerebral palsy and non-rigid equinus will include in this study.

Findings may optimize the use of orthotics and could be integrated in clinical practice. Thus, treatment with braces could be optimized with greatest possible effectiveness and less limitation for the child.

Brief Summary in Scientific Language

Spastic equinus is one of the most common problems in children with cerebral palsy. The calf muscle is shortened and weak which impair walking and results in structured deformities without treatment. Conservative interventions should prevent surgical lengthening on the calf muscle.

Currently immobilization of the stretched calf using braces is a popular treatment of non-rigid equinus. The goal is to improve the range of motion of the ankle through the elongation of the muscle-tendon unit. Recent studies have shown an improvement of passive range of motion and that patients changed their initial contact from toe to heel. This is due to a compensation of the elasticity of the gastrocnemius tendon, which is already too long compared to typical developed children. Thus, bracing doesn't seem to lengthening the fascicle of the gastrocnemius as expected. So far there is a lack of imaging information of the Soles muscle in this context. In Addition, the wearing time of braces wasn't capture instrumentally.



To our best knowledge, the effect of daytime use in addition to braces during night has not been investigated. This could lead to a considerable impact of the compliance of the wearing time of braces and of the dynamic stress of the leg. To stretch the gastrocnemius muscle it is reasonable to extend the knee by using a knee-ankle-foot orthoses at night. Moreover information is missing about the passive stiffness of the plantar flexors as well as the ability of generating force. The goal of this longitudinal study is to investigate the effect of orthotic concepts for spastic equinus on gait, muscle morphology, power generation and passive stiffness of the plantar flexors.

This study will include a comparison between knee-ankle-foot-orthoses during night and knee-ankle-foot-orthoses during night with additionally daytime use. Eighty-six children (n=43 each group) with cerebral palsy and non-rigid equinus will include in this study.

We hypothesize that patients with additional daytime use change their initial contact significantly more from toe to heel than patients wearing braces only at night.

We expect that fascicle length and thickness of M. gastrocnemius would decrease more with additionally daytime use, because patients may not be exposed to eccentric stress that influences the sarcomere genesis positively. Thus, due to reduced fascicle length und muscle thickness active force generation of plantarflexors would decrease more with additional daytime use.

Findings may optimize the use of orthotics and could be integrated in clinical practice. Thus, treatment with braces could be optimized with greatest possible effectiveness and less limitation for the child.

Organizational Data

- DRKS-ID: **DRKS00014696**
- Date of Registration in DRKS: **2018/06/04**
- 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.: **4/18 S , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **G80.1 - Spastic diplegic cerebral palsy**
- ICD10: **M21.62 - [generalization M21.6: Other acquired deformities of ankle and foot]**

Interventions/Observational Groups



- Arm 1: **Knee-ankle-foot orthoses, wearing time at night (Company Pohlig). Intervention for 12 weeks**
- Arm 2: **Knee-ankle-foot orthoses, wearing time at night. Without adaptable knee part for daytime use (Company Pohlig). Intervention for 12 weeks**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

**3D gait analysis: landing angle - foot to floor.
Measurement before and after treatment**

Secondary Outcome

- 1) **3D gait analysis:
velocity, max. dorsiflexion in late stance, max. ankle moment, ankle power**
- 2) **Ultrasound:
Muscle belly length, Muscle belly thickness, Fascicle length, Fascicle angle,
Tendon length**
- 3) **Force of plantarflexors**
- 4) **Passive stiffness of plantarflexors**
- 5) **Wearing time (Orthotimer)**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- Medical Center **Orthopädische Kinderklinik Aschau, Aschau im Chiemgau**



Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/06/04**
- Target Sample Size: **86**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **4 Years**
- Maximum Age: **14 Years**

Additional Inclusion Criteria

Children with spastic cerebral palsy, hemiplegic and diplegic, GMFCS-level I-II, age ranged from 4 to 14 years, non-rigid equinus (it is defined as tone on the modified Ashworth Scale (MAS) max. 3 and a lack of passive range of motion smaller than -10 degree dorsiflexion)

Exclusion criteria

Inability to follow verbal instructions, previous surgery to the leg within 1 year, botulinum toxin injections within 6 months, leg length discrepancies more than 2 cm, lack of passive range of motion greater than -10 degree of knee flexion from neutral

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

■ Private sponsorship (foundations, study societies, etc.)

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URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- 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.