Orientation of lower limb joint-axes during gait in children with cerebral palsy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21545

Source
NTR

Brief title
Orientation of lower limb joint-axes during gait in children with cerebral palsy

Health condition

Cerebral Palsy

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Interreg (2 Seas Mers Zeeën)

Intervention

Outcome measures

Primary outcome

The primary objective of this research is to identify the orientation of the ankle, knee and hip joint axes of rotation (flexion-extension) with respect to the walking direction during gait and standing in children with CP. The orientation of the lower limb joint axes during stance phase

of the gait cycle and the orientation during stance will be compared using a Pearson correlation and Bland-Altman analysis.

Secondary outcome

The secondary objective is to compare the orientation of the these joint axes during gait and standing in children with CP with a Pearson correlation and Bland-Altman analysis . In addition, we will determine the Pearson correlation and Bland-Altman analysis between the tibia and femoral torsion as measured during the clinical examination, the femoral anteversion angle from x-ray and the orientation of the axes during gait and standing.

Study description

Background summary

Rationale: One of the most common disabilities in childhood is Cerebral Palsy (CP). Musculoskeletal problems such as spasticity and joint deformities are frequently seen within CP patients. As a consequence, joint movement axes are rotated relative to each other in the transverse plane. The malalignment of rotation axes leads to deviated gait patterns and limited self-mobility in approximately 50% of the children with CP.
Robotic devices can provide gait training with intensive, controlled, repetitive, and goal-oriented movements with promising results for adults and children. Within the current robotic devices, the axes of rotation for flexion around the ankle, knee and hip are nearly perfectly parallel aligned in the transversal plane. Therefore, they are not optimal for children with CP with joint deformities. A possible solution could be adjustable axes of rotations within the design of the robotic devices. In order to define the minimally needed ranges for adaptable axes of rotation, it is important to determine the orientation of the lower limb joint axes with respect to the walking direction in children with CP with joint deformities.
Objective: The primary objective of this research is to identify the orientation of the ankle, knee and hip joint axes of rotation (flexion-extension) with respect to the walking direction during gait and standing in children with CP. The secondary objective is to determine the correlation between the orientation of the these joint axes during gait and standing in children with CP. In addition, we will determine the correlation between the tibia and femoral torsion as measured during the clinical examination, the femoral anteversion angle from x-ray and the orientation of the axes during gait.
Study design: Retrospective cross-sectional study.
Study population: CP patients, Gross Motor Function Classification System (GMFCS) level II-IV, 8 - 12 years old at time of 3D Gait Analysis (3DGA).
Intervention: not applicable.
Main study parameters/endpoints: The main study parameter is the mean and variation of the orientation the lower limb joint axes with respect to the walking direction during gait (during the stance and swing phase separately) and standing from 3DGA.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients have already had the 3DGA and all clinical tests for clinical purposes.

Participating in the study does not involve any procedures. Therefore, no risks are identified and no burden is associated with participation. Patients do not directly benefit from participating but participation does increase knowledge about the orientation of the lower limb joint axes with respect to the walking direction in children with CP with joint deformities.

Study objective

It is hypothesized that the orientation of the lower limb joints are not parallel to the walking direction and that a standing measure is highly correlated with the orientation during the standing, load bearing, phase of the gait cycle.

Study design

Retrospective data analysis; no time points.

Contacts

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Eligibility criteria

Inclusion criteria

- Diagnosed with CP, Gross Motor Function Classification System (GMFCS) level II-IV
- Age 8-12 years at the time of performing the 3DGA
- Available 3DGA, with signed informed consent to use the data for research purposes
- Available clinical examination (tibial torsion, femoral torsion, femoral anteversion angle)

Exclusion criteria

- Use of a stance correcting walking aid (for example ankle foot orthosis or orthopedic shoes)

during 3DGA

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2021
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-01-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9170
Other	CMO regio Arnhem-Nijmegen : 2020-6561

Study results