Bone deformities in patients with cerebral palsy

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Ethical review	Approved WMO
Status	Pending
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON35180

Source
ToetsingOnline

Brief title
Bone deformities in cerebral palsy

Condition

- Bone disorders (excl congenital and fractures)
- Movement disorders (incl parkinsonism)

Synonym
anatomical variation in bonestructures, Deformities of the bones

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AMC

Intervention

Keyword: Anatomy, Bone deformity, Cerebral Palsy

Outcome measures

Primary outcome

A quantitative and standardized description of the variations of the proximal carpal bones and radius and ulna is made using a statistical shape model. 15000 corresponding points on all registered bone surfaces are automatically established by subsampling the segmented bone surfaces (van de Giessen et al., 2009). Using principal component analysis (PCA), multidimensional variations are described that are present in both the spastic wrist and the contra-lateral (non-spastic) wrist By studying the distributions of the parameters that specify these variations, we can describe the prevalence of certain shape variants and detect shape differences between the spastic and contra-lateral wrist.

Secondary outcome

n/a

Study description

Background summary

Patients with spastic cerebral palsy (sCP) typically present with an impaired range of motion that affects the positioning of the upper extremity. The motor disorders of sCP are often accompanied by secondary musculoskeletal problems (Rosenbaum et al., 2007) which limit the functioning of the hand and arm. Generally, the extreme wrist flexion and ulnar deviation position develops well before adolescence. Consequently, the bones of the wrist develop under pathological loads.
The proximal carpal bones play important roles in the mobility of the wrist

(Craigen and Stanley, 1995, Garcia-Elias et al., 1995). Relations have been found between the bone shapes and their kinematics (Nakamura et al., 2000). In the area of reconstructive surgery, the ability to recover functional wrist mobility depends on the estimated non-pathological bone shapes (Craigen and Stanley, 1995, Crisco et al., 2005). Recently, a statistical shape model has been developed with which the shapes of the bones of the wrist can be described using CT scans (van de Giessen et al., 2010, van de Giessen et al., 2011). With these descriptions, we can study the influence of spastic control on bone growth in the spastic wrist. Ultimately, this information can tell us something about the development of postoperative wrist pain in sCP patients.
The aim of our study is to evaluate the degree of anatomical variation of the wrist bones as a consequence of spastic control. We also want to compare degree of anatomical variation with that of the unaffected wrist.

Study objective

The aim of this study is to evaluate the influence of extreme fixed wrist flexion and ulnar deviation due to spasticity on bone shapes of the wrist bones. We want to compare CT scan-based three-dimensional reconstructions of the spastic wrist to the contralateral, healthy wrist in hemiplegic patients.
We hope to gain valuable anatomical information and to create a basis for further research in studies on various wrist pathology and surgical techniques.

Study design

An observational study and anatomical study.

Study burden and risks

The radiation exposure of scans is estimated to be 0,6 mSv for each participant. This is comparable to 12-14 weeks background exposure to the natural radiation in The Netherlands.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Hemiplegic cerebral palsy
- Tendon transfer surgery at our institution in the years 2000-2010
- Over the age of 18 years
- Unaffected contralateral wrist

Exclusion criteria

- Extrapyramidal symptoms
- Not able to understand the written informed consent
- Pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2011
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL38330.018.11