Madelung deformity

Published: 08-01-2019
Last updated: 11-04-2024

Investigate anatomy, kinematics, clinical outcomes, and functional outcomes in Madelung deformity patients.In this study we will answer the following 3 questions:1) What is the anatomical situation of the wrist in patients with Madelung deformity,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON45925

Source
ToetsingOnline

Brief title
Madelung deformity

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
congenital deformity of the wrist, Madelung deformity

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diagnostic imaging, growth disorders, hand deformities, osteotomy

Outcome measures

Primary outcome

Anatomy (shape of radius, shape/position of carpal bones) and kinematics (displacement/rotation of carpal bones during movement) are assessed using 4D CT imaging.

Secondary outcome

Clinical outcomes of the wrists are assessed through physical examination, measuring: flexion, extension, pronation, supination, radial deviation, ulnar deviation, and grip strength.

Functional outcomes are assessed using the Michigan Hand Outcomes Questionnaire (MHOQ) and the EuroQol EQ-5D-5L questionnaire.

Study description

Background summary

Madelung deformity is a rare congenital deformity of the wrist. The deformity is characterized by a palmar subluxation of the hand, a prominent distal ulna, and volar angulation of the distal radial epiphysis. Currently, we know that the deformity is caused by an abnormal growth arrest of the distal radial epiphysis leading to volar and ulnar tilting of the radial articular surface, and palmar bowing of the distal radius. Because of its progressive nature, the deformity can lead to wrist pain, restricted range of motion (ROM), and loss of grip strength, heavily interfering with daily activities. Additionally, patients can complain about the visible deformity caused by prominence of the distal ulna. Madelung deformity often occurs bilaterally, is most often diagnosed in adolescent females, and has been associated with genetic disorders such as Léri-Weill dyschondrosteosis (LWD) and Turner syndrome.

Representing less than 2% of pediatric hand deformities, our current understanding of this condition is limited. This is also reflected in patient care, as multiple surgical procedures have been proposed to correct the

deformity, without a current consensus. Therefore, nearly 200 years after its original description, a significant knowledge gap remains, with respect to etiology, surgical management and outcomes of Madelung deformity patients, compromising patients' access to optimal care.

To find the best treatment for patients it is of the utmost importance to understand the complex anatomical situation and corresponding wrist biomechanics. Due to recent innovations it is now possible to capture wrist anatomy during movement using 4-Dimensional (4D) Computed Tomography (CT) imaging, a technique which our group has applied in multiple previous studies.

Study objective

Investigate anatomy, kinematics, clinical outcomes, and functional outcomes in Madelung deformity patients.

In this study we will answer the following 3 questions:
1) What is the anatomical situation of the wrist in patients with Madelung deformity, and how does this differ in comparison to healthy wrists?
2) How is the movement of carpal bones in patients with Madelung deformity, and how does this differ in comparison to healthy wrists?
3) What are the clinical and functional outcomes before and after different surgical treatment options?

The answer to these questions can be used to better understand the pathophysiology of Madelung deformity. In addition, our data can be used to identify the optimal treatment plan through quantification and comparison of objective/subjective outcome measurements. Ideally, our results will lead to a personalized treatment protocol.

Study design

Observational cohort study.

Study burden and risks

Not applicable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients, 16 year and older, diagnosed with Madelung deformity.

Exclusion criteria

- Other bony deformities of the ipsilateral distal forearm.
- Not able to understand the written consent.
- Pregnancy.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2019
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	08-01-2019
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	NL66957.018.18