The effect of dorsally directed pressure on the pisiform on carpal movements at midcarpal instability

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To assess the influence of external pressure on the os pisiforme on carpal movements in patients with midcarpal instability

Ethical review	Approved WMO
Status	Pending
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON31484

Source
ToetsingOnline

Brief title
midcarp.1

Condition

- Tendon, ligament and cartilage disorders

Synonym
midcarpal instability, wrist instability

Research involving
Human

Sponsors and support

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

Intervention

Keyword: instability, midcarpal, pisiform, wrist

Outcome measures

Primary outcome

The X-ray videos will be analysed using the AMC protocol. We will quantify the

pressure needed to cancel the sudden carpal movements of the proximal row

('catch-up-clunk') in ulnar and radial deviation.

Secondary outcome

n.v.t.

Study description

Background summary

The wrist is a complex joint composed of eight carpalia which are mutually linked by ligaments. In a normal situation the ligaments keep the carpalia in a correct position during the movements of the hand. However, in case of loose ligaments it is possible that the carpalia move suddenly to their new position, instead of moving fluently.
This phenomenon is known as: *midcarpal instability*. It causes pain, a sense of blockade and sometimes a clearly audible, dull click (*catch-up-clunk*). Currently there is no good treatment available, therefore numerous patients are strongly limited in their daily activities for a long period, such as hobby*s, sports and work.
Lichtman et al. describes that external dorsally directed pressure on the os pisiforme may normalise the aberrant movements of the carpalia, which would lead to a decrease in wrist disturbances. This theory has never been objectified. If the external pressure on the os pisiforme has actual effect on the carpal movements, what we expect, it will be a basis to develop a dynamic splint. This could be a new, founded therapy for midcarpal instability, which we will evaluate in follow-up studies.

Study objective

To assess the influence of external pressure on the os pisiforme on carpal

movements in patients with midcarpal instability

Study design

In this pilot-study we will asses under videofluoroscopy the difference of carpal movements in a group of persons without and with carpal instability under the influence of an external exerted pressure on the pisiform bone. We have developed an X-ray translucent instrument which gives an uniformly distributed external pressure on the os pisiforme in every position of the hand. The forearm will be fixed on the instrument using belts. A lever connected to the skin with a small silicon cup will give an external dorsally directed pressure on the os pisiforme. This pressure will not be unpleasant for the patients. We will observe the effect of the dorsally directed pressure on the carpal movements with X-ray videos (videofluoroscopy) and describe our results in an article.

Intervention

Every patient cq. healthy person will go three times through the cycle of ulnair to radial deviation. Everytime we will make an X-ray video. The patient moves his hand himself. We will repeat this process with three different external pressures on the os pisiforme.

Study burden and risks

The duration of this videofluoroscopy examination will not exceed half an hour. The pressure on the os pisiforme will be that low that it will not be unpleasant or riskful, probably it will relieve the pain of the patients with midcarpal instability. The load of radiation is a category I (<0,1 mSV) of the ICRP62: trivial risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

midcarpal instability

Exclusion criteria

pregnancy, children (<18yrs), radiologic employees, participation in a scientific examination with radiologic exposure within the last 12 months.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-11-2007
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	A X-ray translucent instrument which gives a measurable external pressure on the pisiform
Registration:	No

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	NL19785.018.07