

Follow-up MRI after conservative treatment of a complete rupture of the ulnar collateral ligament

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To investigate what the radiological findings on MRI are after a minimum of six months conservative treatment of a complete rupture of the ulnar collateral ligament of the thumb.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON45926

Source

ToetsingOnline

Brief title

Follow up MRI UCL trial

Condition

- Tendon, ligament and cartilage disorders

Synonym

gamekeeper's thumb, skier's thumb

Research involving

Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum

Source(s) of monetary or material Support: subsidie van Landsteiner instituut/wetenschapsfonds van MC Haaglanden

Intervention

Keyword: conservative treatment, MRI, Thumb, UCL

Outcome measures

Primary outcome

Radiological findings on the MRI scan:

- level of healing of the UCL
- formation of scar tissue
- possible abnormalities

Secondary outcome

not applicable

Study description

Background summary

A partial or complete rupture of the ulnar collateral ligament of the metacarpophalangeal joint of the thumb, skier's thumb, is an often-encountered problem. It concerns 86% of all injuries to the base of the thumb. The estimated incidence in the US is approximately 200,000 patients per year. The incidence in the Netherlands is not known. In the last four years, we have diagnosed approximately 85 patients in our own hospital. Skier's thumb is the result of a hyperabduction trauma of the thumb. It can occur with any fall on an outstretched hand when a thumb that is already in abduction receives an extra valgus stress. Skier's thumb refers to the fact that this injury is often seen in skiers who fall while holding on to their ski poles. This type of injury is also seen in other sports, especially those that use a stick or ball, such as hockey or basketball. During a query in our own inner-city hospital, only 10% of the patients had skier's thumb due to an injury acquired during skiing. Often, these patients also presented with a delay because their injury occurred during a holiday, and they waited until they came back home to see their own physician. A fall on the hand, usually from a bicycle or motorcycle (in which the thumb gets stuck behind the handlebars), is the most common cause of skier's thumb in our hospital, seen in approximately 40 % of all patients. Another sport, especially soccer or fighting, was the cause in 30%.

The ulnar collateral ligament is made up of two parts, the proper collateral ligament (PCL) and the accessory collateral ligament (ACL). The PCL has its origin proximal to the base of the head of the MCP-1 joint and insertion on the volar side of the proximal phalanx. The ACL has its origin just palmar of the PCL and runs parallel to the PCL to its insertion on the proximal phalanx. Together they ensure the ulnar and volar stability of the base of the thumb. However, there are other components that also take part in creating stability in the joint. They can be divided into static and dynamic components. The most important dynamic component is the adductor pollicis muscle. This muscle has its insertion

onto the proximal phalanx partly superficial to and partly deeper than the UCL. Most of the time, the distal end of the UCL ruptures. A Stener lesion occurs when this part gets stuck between the proximal edge of the still intact aponeurosis of the adductor. Because this aponeurosis stands between the UCL and the bone, it is thought that this injury cannot heal in this position. Stener lesions occur in 64% to 87% of all complete ruptures and are usually treated by surgical repair. If the MCP joint is in flexion, the PCL and the dorsal capsule are taut and therefore the most important stabilizers in that position. The reverse applies to the ACL and the volar plate, which are taut when the MCP is in extension.

The first step in diagnostic imaging studies is to make a plain radiograph in the AP and lateral direction to diagnose an avulsion fracture that is mostly located on the ulnar side of the proximal phalanx. If the plain radiograph shows no avulsion fragment but there is a clinical suspicion of skier's thumb, further imaging can be performed by doing an ultrasound, CT, arthrogram or MRI. Which technique to use seems to be determined by the physician's preference; there are no clear guidelines about this. MRI can be seen as a gold standard with a sensitivity of 96%-100% and specificity of 95-100%.

If no firm endpoint is found during testing, surgery is considered the best treatment. This also applies to Stener lesions because the general idea is that the UCL cannot heal if it is not in contact with its insertion, even though no evidence can be found in the literature to support this notion.

Some small prospective studies have been performed that show good outcomes for patients with a complete rupture of the UCL that had conservative treatment. Also, operative repair, though having a high success rate, also has a small risk of nerve injury. This is why the UCL-trial was set up, a multicenter randomised controlled trial, to investigate whether conservative treatment of this injury is equal to operative repair.

In this study, we want to make a follow up MRI scan of the UCL-trial patients that had a conservative treatment of their injury. This way, we have an objective and easily repeatable test to assess the level of recovery of the UCL.

Study objective

To investigate what the radiological findings on MRI are after a minimum of six months conservative treatment of a complete rupture of the ulnar collateral ligament of the thumb.

Study design

A descriptive study, in which patients from the aforementioned UCL trial that were randomised into the conservative treatment group, will now get a followup MRI scan of the thumb.

Study burden and risks

Patients will have to visit the hospital once to have the MRI scan made, this will be a maximum of 30 minutes. The MRI scan itself does not emit harmful radiation. Risks are not thought to be present in this study.

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

Patients that were included in the UCL trial and were randomised into the 'conservative treatment' group, minimum of 6 months after injury

Exclusion criteria

Patients not participating in UCL trial, people that were randomised into surgical group, people < 6 months after injury

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 14-02-2017

Enrollment: 5

Type: Actual

Ethics review

Approved WMO

Date: 29-08-2016

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 22-02-2017

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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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	NL57686.098.16