Scapholunate ligament reconstruction without immobilisation

Published: 01-03-2024
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To demonstrate that immediate fixation leads to a shorter total rehabilitation period and to less stiffness at final follow-up after SL reconstruction.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON56631

Source
ToetsingOnline

Brief title
SL reconstruction without immobilisation

Condition

- Bone and joint therapeutic procedures

Synonym
scapho-lunate ligament injury

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Arthrex Research

Intervention

Keyword: immobilization, internal brace, scapholunate ligament

Outcome measures

Primary outcome

In both groups, mobility (flexion and extension, E-link) will be assessed at

baseline, six weeks and three, six and twelve months postoperatively.

Secondary outcome

In both groups, pain intensity (VAS), strength (Jamar grip strength) and

function (PRWHE-DLV, quickDASH) will be assessed at baseline, six weeks and

three, six and twelve months postoperatively.

Study description

Background summary

Following scapho-lunate ligament (SL) reconstruction, a six month rehabilitation period is required. In the standard procedure, SL and SC are secured with K-wires and the wrist is immobilized for six weeks in an upper-arm cast. Applying bio-tenodesis screws for immediate fixation of the tendon graft to the scaphoid and lunate enables skipping the six week K-wire and cast immobilization. Our hypothesis is that the immediate fixation leads to a shorter total rehabilitation period and to less stiffness at final follow-up after SL reconstruction.

Study objective

To demonstrate that immediate fixation leads to a shorter total rehabilitation period and to less stiffness at final follow-up after SL reconstruction.

Study design

Randomized controlled trial.

Intervention

Fifty patients will be included in this study. Through randomization, 25 patients will be treated by means of the standard procedure and 25 patients

will be treated with the immediate fixation technique.

Study burden and risks

The duration and burden of the operation will be the same in each group. The standard procedure requires 6 weeks immobilisation, whereas patients in the immediate fixation technique group will be immobilised for one week. The standard rehabilitation period has a 6 month duration and taking part in the study puts no extra burden on patients in this six month period. The final assessment, however, will be at twelve months requiring an extra visit to the hospital.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Age 18 to 65 years
Arthroscopically confirmed SL injury of at least Geissler 2

Exclusion criteria

Presence of SLAC (arthritis)
Another condition affecting the function of the diseased or contralateral extremity
Inability to speak the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-04-2023
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-03-2024
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL83629.042.23