PROspective Minimally Invasive Surgery of the toes
A prospective cohort study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON55493

Source
ToetsingOnline

Brief title
PROMIS-Trial

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
deformity of the toes, Rigid claw toes

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Innovatie & Wetenschapsfonds Isala

Klinieken;Zwols Wetenschapsfonds Isala Klinieken

Intervention

Keyword: Minimally Invasive Surgery (MIS), Rigid claw toes

Outcome measures

Primary outcome

The primary outcome measure is the Foot Function Index (FFI) after 2 years. The FFI is a patient reported outcome measure.

Secondary outcome

Secondary outcome measures include the AOFAS (Lesser Metatarsophalangeal-Interphalangeal Scale), NRS pain score, NRS satisfaction score and return to work/activities. Furthermore, failure and complication rates are assessed, as are perioperative variables. Furthermore, a prediction model for FFI outcome will be created to assess which patiënts are most suitable for the MIS technique.

Furthermore. a learning curve assessment will be done based on two year FFI scores, AOFAS score, NRS pain score and NRS satisfaction score. Aditionally, assessment of the effect size (treatment effect) will be done by comparing preoperative scores to postoperative scores at the various time points.

Study description

Background summary

The results of traditional open claw toe surgery, in which large incisions are used, are reasonably satisfying, but complication rates are high. In response,

minimally invasive surgery (MIS) techniques have been developed that are aimed to do as little damage as possible to the surrounding tissues. The results of minimally invasive foot surgery look promising: good functional outcome and low complication rates are reported. However, most studies that advocate minimally invasive foot surgery techniques are small retrospective case series.
Regardless of this serious lack of knowledge, more and more patients in the Netherlands request to be treated with this technique, and an increasing number of orthopedic surgeons have adopted MIS claw toe surgery into their daily practice. This is problematic - even potentially dangerous - because it is currently unknown how the results of the MIS technique are compared to the results of the traditional technique. The few small retrospective studies provide no reliable evidence on the safety and efficacy of this technique. Furthermore, there is no data that provides any insight into what the indications for this technique should be, and for which patients the MIS technique might not be suitable. From the surgeons* point of view, there is a serious lack of knowledge regarding a potential learning curve and what pitfalls should be avoided when this technique is adopted into standard care.
In summary: MIS-techniques are currently being implemented as standard treatment without being backed by proper scientific evidence.
The PROMIS-Trial is designed to solve these very important problems and provide the necessary evidence that we desperately need to decide if and how we should start using this technique for the treatment of rigid claw toes. The PROMIS-Trial consists of two parts and is aimed to answer three important questions:
• What is the outcome and foot function after minimally invasive claw toe surgery?
• For which patients should minimally invasive claw toe surgery be used (can we predict what patients are likely to have a good outcome)?
• Is there a learning curve for minimally invasive claw toe surgery?

Study objective

The primary objective is to assess the outcome of treatment of rigid claw toes with the MIS technique in terms of the Foot Function Index (FFI), measured two years postoperatively.
The secondary objective of this study is to assess the outcome of treatment of rigid claw toes with the MIS technique in terms of AOFAS score, NRS pain score, NRS satisfaction score and return to work/activities, measured at four weeks, three months, one year, two years and five years postoperatively. Additionally, the FFI will be measured after four weeks, three months, one year and five years postoperatively. Another objective is to create a prediction model (multiple linear regression model) for FFI outcome two years postoperatively after MIS surgery, based on preoperative variables.

Furthermore, we assess to what extent a learning curve exists for surgeons during the first 10 surgeries after completing the GRECMIP courses by curve-fitting of the two years postoperative FFI scores (plotted per #

performed surgeries) in comparison to a predefined level of expertise (the FFI scores of the experienced surgeons), and to assess individual learning curves using CUSUM analysis and by assessing mean FFI scores per 5 subsequent surgeries (surgery 1-5, 6-10, +11)
Furthermore, we assess treatment effect of MIS surgery (measured using PROMs).

Study design

The PROMIS-Trial is a multicenter prospective cohort study in which 100 patiënts will be prospectively enrolled who will undergo minimally invasive claw toe surgery.
The inclusion period is estimated at 4 years. Follow-up appointments will be after 4 weeks, 3 months, 1 year, 2 years and 5 years. Therefore, the total duration of the study is approximately 9 years.

Intervention

For patients in Part I the study group will be treated according to the minimally invasive technique as described by De Prado et al., the control group will be treated with traditional open surgery.
Patients in Part II will all be treated with the MIS technique as described by De Prado et al.

Study burden and risks

Patients fill out questionnaires at every standard follow-up appointment, which will take approximately 10 minutes. Two extra appointments (after 2 and 5 years) are planned as follow-up in this study. This is a minor burden compared to the relevance of this study.

Although there is an absence of high-quality evidence on the efficacy and safety of this technique, MIS aims to do as little damage as possible to avoid complications of traditional open surgery by performing the established treatment concepts (such as tenotomies and osteotomies) through smaller incisions and less traumatic procedures. Especially potentially damaging complications such as infections, DVT, nerve damage and necrosis are rare compared to open surgery.

Compared to patients that are treated with the MIS technique outside of this study, there is no extra risk associated with study participation, and perhaps even a slight risk reduction. When patiënts do not participate, they'll recieve the same treatment.
Patients in Part II are exposed to a minor risk compared to patients that are treated with the traditional technique, due to the absence of high-quality evidence on the efficacy and safety of this technique. However, all participating surgeons are guaranteed to have received adequate training (all

experienced foot- and ankle surgeons in Dutch hospitals and clinics), which certainly cannot be guaranteed outside this study, expecially in foreign clinics that many patients currently go to for their MIS surgery.
The researchers believe that the risks of this study are negligible, and justified.

The PROMIS-Trial is essential to study the outcome of the MIS technique because these techniques are being implemented everywhere without being backed by proper evidence from large trials. The value of this study is very high and more than justifies the minor possible extra risks.

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

- Age >=18 and <=75
- Symptomatic rigid claw toes, according to the definition by Schrier et al. (2009)
- Indication for surgical treatment

Exclusion criteria

- Standard contraindications for claw toe surgery (e.g. active infection, inadequate vascular supply)
- Inability to understand or correctly interpret the questionnaires (mental retardation, language barrier)
- Previous foot surgery on the ipsilateral foot
- Concomitant surgery on the ipsilateral foot (e.g. hallux valgus surgery, bunionette)
- Unlikely to comply with the long follow-up (e.g. severe comorbidity, impaired life expectancy)
- Comorbidity that affects foot function (e.g. severe neuropathy, paralysis, severe osteoarthritis of the foot or ankle (Kellgren-Lawrence score >3), symptomatic hallux valgus)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-10-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	09-11-2017
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	11-10-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	14-10-2021
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL57994.075.17