The treatment of moderate to severe onychocryptosis with either a wedge resection with or without phenolization or partial nailmatrix resection with phenolization, a randomized controled trial.

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The objectification of the most effective surgical treatment, in which three operationprocedures are compared.

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON40435

Source
ToetsingOnline

Brief title
Treatment of onychocryptosis

Condition

- Skin and subcutaneous tissue disorders NEC
- Skin and subcutaneous tissue therapeutic procedures

Synonym
ingrown toenail, inguis incarnatus

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Stichting Zwols Wetenschapsfonds Isala klinieken

Intervention

Keyword: ingrown toenail, onychocryptosis, partial nailmatrix resection, unguis incarnatus, wedge resection

Outcome measures

Primary outcome

relief of symptoms

regrowth of nails spicula

recurrence onychocryptosis

Secondary outcome

healing time

Postoperative complications (hemorrhage / infection)

Postoperative pain

patient satisfaction

Study description

Background summary

Ingrowing toenails, also known as *onychocryptosis* or *unguis incarnatus*, are a common problem among the general population with a prevalence of 54/10,000 registered patients per year, with a peak between 15 and 24 years of age in Dutch general practice.(DeLauro and DeLauro 2004; Westert, Schellevis et al. 2005) Ingrowing toenails occur when the periungual skin is punctured or traumatized by one of the distal angles of the nail plate. This results in a cycle of invasion by foreign bodies, which is sometimes followed by infection

with signs of inflammation and then repair processes. The person develops a painful and draining lesion, with the formation of granulation tissue at the side of the puncture.(Eekhof, Van Wijk et al.; Heidelbaugh and Lee 2009) These symptoms cause a great deal of discomfort, and they often have an impact on everyday activities. (Yang, Yanchar et al. 2008)

The most important cause for onychocryptosis is improper trimming of the nail. Other common causes are tearing nails off, wearing tight shoes. Also the position of the toe can cause an ingrown toenail. Diabetes, obesity, oedema of the lower extremities, hyperhidrosis plantares, and heart, renal and thyroid diseases are risk factors for developing onychocryptosis.(Heidelbaugh and Lee 2009)

There are three stages to classify onychocryptosis: mild (I), moderate (II) or severe (III). The mild stage is characterized by nail-fold swelling, oedema, erythema and pain. The moderate stage has the symptoms as in the mild stage, but this stage leads also to inflammatory granulation tissue, infection, seropurulent exudate and sometimes ulceration of the nail-fold. In the severe stage the inflammation is chronic, granulation tissue and sometimes nail-fold hypertrophy occurs.(Eekhof, Van Wijk et al.; Gerritsma-Bleeker, Klaase et al. 2002; DeLauro and DeLauro 2004)

There are several interventions for onychocryptosis. The group of non-surgical interventions includes gutter treatment, orthonyxia, band-aid method, soaking the toe in warm water, placing a piece of cottonwool under the ingrowing toenail. These options are mostly used in the mild or moderate stages.(Eekhof, Van Wijk et al.; Heidelbaugh and Lee 2009) The group of surgical interventions includes radical excision of the nail fold (*Vandenbos procedure*), rotational flap technique of the nail fold, wedge excision (*Winograd*), partial nail avulsion (PNA, *Ross*).(Ross 1969; Winograd 2007) The last three treatments can be combined with chemical, surgical or physical (electrofulguration) excision of the matrix. The chemical matricectomie is an application of a corrosive liquid, like phenol or sodium hydroxide. The surgical interventions are used in the moderate or severe stages.

A recent meta-analysis concluded that surgical interventions are more effective than non-surgical interventions with gutter treatment in preventing recurrence of the ingrowing toenail.(Eekhof, Van Wijk et al.) One of the conclusions is that the addition of phenol to a radical wedge resection is more effective in preventing recurrence and regrowth than wedge resection alone.(Eekhof, Van Wijk et al.) However, this conclusion is based on only one randomized controlled trial from 1988.(Issa and Tanner 1988)
In our hospital, the Isala Clinics Zwolle, every surgeon uses one of the above described techniques: radical wedge resection, partial nail avulsion with phenolisation of the nail matrix or a wedge resection with phenolisation. However regrowth of nail spikes or recurrence of onychrocryptosis does occur. Based on the conclusion of the meta-analysis we started this randomized

controlled trial to investigate the benefit of additional phenolisation after a radical wedge resection.

Our research question is if phenolisation in addition to the surgical wedge resection in patients with moderate to severe onychocryptosis, has an effect on the occurrence of regrowth of nailspikes and recurrence of onychocryptosis. Secondary outcome measures are postoperative pain, postoperative analgesic use, postoperative haemorrhage and patient*s satisfaction 6 months after surgery.

Study objective

The objectification of the most effective surgical treatment, in which three operationprocedures are compared.

Study design

a single blinded randomized controled trial

Intervention

wedge resection
wedge resection with phenolization
nailmatrix resection with phenolization

Study burden and risks

no additional risks for patients participating in this study compared to no participation.

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

Indication for surgical treatment of moderate and severe onychocryptosis not responsive to conservative treatment

Exclusion criteria

diabetic ulceration of the feet
periferal vascular disease
prior surgery of the toe

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2013
Enrollment:	400
Type:	Anticipated

Ethics review

Approved WMO

Date:	14-10-2014
Application type:	First submission
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	NL44569.075.13