Local steroids for triggerfingers

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26599

Source
NTR

Brief title
triggertrial

Health condition

Tenosynovitis

Sponsors and support

Primary sponsor: Jeroen Bosch Hospital,
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Primary Objective: The primary outcome to be compared is the success rate of Kenalog-40, Kenalog-10 and Depo-Medrol 40 mg/ml in the treatment of a trigger finger. Success rate is defined as no persistent or recurrence of a trigger finger after injection (maximum three injections). We hypothesize that Depo-Medrol 40 mg/ml has the highest success rate (considering rate of persistence, recurrence and amount of injections) and Kenalog-10 is lowest success rate. We expect less difference between Depo-Medrol 40 mg/ml and Kenalog-40 than between Kenalog-40 and Kenalog-10.

Secondary outcome

- Difference in patient reported outcomes (MHOQ and NRS scores)
- Difference in ROM before and two months after injection
- Difference in costs
- Difference in number and kind of complications
- Difference in quinnell primary result after 1, 2 or 3 injection
- Difference in after how many injections(1,2 or 3) the treatment is considered a success in the three different research arms.

Study description

Background summary

Rationale: Trigger finger (stenosing tenosynovitis) is one of the most common conditions seen by hand surgeons, with a lifetime risk estimated at 2.2% in the general population. Literature shows that corticosteroid injection therapy is safe and highly effective (long-term effectiveness 69%) in treating trigger fingers.1 The exact mechanism of action remains unclear, but it could be attributed to the anti-inflammatory effect reducing the swelling of the A1 pulley.2 Furthermore, different types of corticosteroid injections are uses and it is not known which is most effective and has the least complications.
The present study is a double-blinded randomized clinical trial to compare Kenalog-10, Kenalog-40 and Depo-Medrol 40 mg/ml in effectiveness (recurrence rate, level of pain, disability and range of motion), costs and complications (number and severity) in treating trigger fingers.
Objective: The study goal is to determine whether Kenalog-10, Kenalog-40 or Depo-Medrol 40 mg/ml is best used in treating trigger fingers with a corticosteroid injection.
Study design: Double-blinded randomised clinical trial.
Study population: In this study we will include all patients with trigger fingers that visit the Plastic Surgery Outpatient Department of the Jeroen Bosch Hospital. Criteria for inclusion are one or more trigger fingers, grade 1-3 trigger finger (according to classification by Quinnell3).
Intervention: Patients will be assigned to the different treatment groups at random. The doctor’s assistant will provide the doctor with a corticosteroid injection labelled ‘1’, ‘2’ or ‘3’, each corresponding to one kind of corticosteroid (Kenalog-10, Kenalog-40 or Depo-Medrol 40 mg/ml) for which the doctor and patient is blinded. According to normal clinical practice, the doctor will insert the injection through the skin at the level of the middle of the A1 pulley and inject the corticosteroid nearby the tendons.
Main study parameters/endpoints: The main objective is to determine the difference in effectiveness of Kenalog-10, Kenalog-40 and Depo-Medrol. The primary outcome to be compared is the success rate (Quinell grade 0: no persistence or recurrence of triggering). Secondary outcomes are patient reported outcomes, (Michan Hand Outcome Queistionairy), level of pain, range of motion, complications, and costs and after how many injections of each corticosteroid there can be considered a successful treatment.
Nature and extent of the burden and risks associated with participation, benefit and group

relatedness: All patients in this study will be voluntary participants and written informed consent will be obtained from all participants. Participants will be given the corticosteroid injection at the exact same way as we always treat patients with trigger fingers. All corticosteroids involved in this study are being used worldwide for years in treating trigger fingers. The risk of harm will be no different for the participants in comparison to regular patients. Published data will be fully anonymised.

Study objective

flexor tenosynovitis of the hand ('trigger finger')

Study design

2 months, 6 months, 12 months.

Intervention

Injection will consist of 20mg kenacort, 5mg kenacort or 20mg depomedrol. Each injection will be combined with 5mg lidocaine. For each type of steroid, 1 cc will be injected per finger.

Contacts

Public
jeroen bosch ziekenhuis
Catherine van den Berg

7774
Scientific
jeroen bosch ziekenhuis
Catherine van den Berg

7774

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- One or more trigger fingers
- Grade 1-3 trigger finger (according to classification by Quinnell)

- Participation is voluntary and with informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Aged <18
- Congenital trigger finger
- Mentally disabled persons
- Grade 4 trigger finger (according to classification by Quinell)
- Allergy for corticosteroids
- Previous surgical release for triggering
- Previous injection therapy
- History of surgical intervention in the same digit

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-04-2020
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
none yet

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 54114
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8511
CCMO	NL73344.028.20
OMON	NL-OMON54114

Study results