Effectiveness of corticosteroid injection in treatment of trigger fingers: a double blinded randomized clinical trial

Published: 04-06-2020
Last updated: 19-03-2025

We hypothesize that Kenalog-40, Kenalog-10 and Depo-Medrol 40 mg/ml have a different effectiveness in treating trigger fingers in both primary as secondary outcomes.

Ethical review	Approved WMO
Status	Completed
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON54114

Source
ToetsingOnline

Brief title
Lokal steroids for triggerfingers

Condition

- Tendon, ligament and cartilage disorders

Synonym
tenosynovitis, triggerfinger

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: de behandeling betreft verzekerde zorg;de analyse van data is eigen tijd.

Intervention

Keyword: depo-medrol, kenacort, Steroids, triggerfingers

Outcome measures

Primary outcome

Primary Objective: The primary outcome to be determined 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 (Quinell 0) of a trigger finger one year after injection (maximum three injections). In addition, the amount of injections needed to achieve Quinnell 0 or the amount of conversions to an operative treatment will be determined for each corticosteroid type of injection. We hypothesize that Depo-Medrol 40 mg/ml has the highest success rate (considering rate of persistence, recurrence and amount of injections and conversion to an operative treatment) 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

Secondary Objectives:

- Difference in patient reported outcomes (MHOQ, TFQ and NRS scores)
- To test the validity and reliability of the Trigger Finger Questionnaire
- Difference in ROM before and two months after injection
- difference in costs
- difference in number and kind of complications

Study description

Background summary

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.

In literature, no patient reported outcome measure (PROM) focused specific on trigger fingers is available. Most validated PROM*s administered to patients with trigger fingers focus on overall upper extremity range of motion, function, limitations in daily life, and patient satisfaction. Other disease specific PROM*s, for instance the Boston Carpal Tunnel Questionnaire (BCTQ) or the Patient Related Wrist Hand Evaluation (PRWHE) are not applicable. We aim to create a disease specific PROM composed of prior validated questions from existing questionnaires complemented with new, trigger finger specific, questions.

Study objective

We hypothesize that Kenalog-40, Kenalog-10 and Depo-Medrol 40 mg/ml have a different effectiveness in treating trigger fingers in both primary as secondary outcomes.

Study design

In order to be able to provide the best possible evidence of whether Kenalog-10, Kenalog-40 of Depo-Medrol 40 mg/ml is best used in treating trigger fingers, we choose a double-blinded randomised clinical trial as study design. Patients will be assigned to the different treatments at random. Both the doctors as the patients will be blinded for the type of corticosteroid injection used. Procedures will be controlled to ensure that all patients are treated the same except for the corticosteroid that is used. Neither the patients nor the investigators will know which corticosteroid is used for each patient.

Intervention
In this study we compare triamcinolone acetonide 10 mg/ml (Kenalog-10), triamcinolone acetonide 40 mg/ml (Kenalog-40) and methylprednisolone 40 mg/ml (Depo-Medrol 40 mg/ml).
As common clinical practice, Kenalog-10, Kenalog-40 and Depo-Medrol 40 mg/ml will prepared by the doctor*s assistant of the out clinic department of plastic surgery in the Jeroen Bosch Hospital and checked by a second dotor*s assistant. The injection syringe will be labelled with a nummer (1,2 or 3) corresponding with the type of corticosteroid which is ad random assigned to a patient. Only the doctor,s assistant is known which type of corticosteroid injection is numberd 1, which is numbered 2 and which is numbered 3, which is registrated in a document that can only be viewed by the doctor*s assistant.

Intervention

There will be injected a corticosteroid in the tretment of triggerfingers. This is the standard treatment for triggerfingers. In our research the treatment is completely simular to the current daily practice.

Study burden and risks

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.

Contacts

Public
Jeroen Bosch Ziekenhuis

henri dunantstraat 1
's Hertogenbosch 5223 GZ
NL
Scientific
Jeroen Bosch Ziekenhuis

henri dunantstraat 1
's Hertogenbosch 5223 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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
- Current pregnancy of breast-feeding

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	26-06-2020
Enrollment:	300
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Depo-Medrone 40mg/ml Suspension for Injection
Generic name:	Methylprednisolone acetate 40 mg/ml
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Kenacort-10
Generic name:	Triamcinolone acetonide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Kenacort-40
Generic name:	Triamcinolone acetonide
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	04-06-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	09-06-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-04-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-04-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26599
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2020-002285-14-NL
CCMO	NL73344.028.20
Other	NL8511
OMON	NL-OMON26599