Double dose treatment: Corticosteroid injection therapy in arthritis

Published: 21-04-2010
Last updated: 02-05-2024

To determine whether doubling the dose of corticosteroid injections in the treatment of arthritis in knee joints is more effective in the relief of symptoms as measured by change in the assessment of arthritis burden by the patient on a Likert 5-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON34658

Source
ToetsingOnline

Brief title
DoDo

Condition

- Autoimmune disorders

Synonym
RA, rheumatoide artritis

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: stichting reuma onderzoek twente

Intervention

Keyword: corticosteroid, local injection, rheumatolgy, triamcinolone

Outcome measures

Primary outcome

Primary outcome: percentage of patients with sustained good response; i.e. symptomatic relief after local corticosteroid injection in knee joint, measured as a difference (a positive change of at least 2 points on a 5 point scale) between t = 0 and t = 12 weeks on a 5 point Likert scale (Burden of arthritis symptoms: very much, much, moderate, little, none; as determined by a question to the patient, see CRF) at at least 2 consecutive weeks including week 12, for each included patient.

Secondary outcome

-% of patients with good response in symptomatic relief at individual weekly time points (at t = 2,3,4,5,6,7,8,9,10,11 weeks) measured as the difference between the time point and t= 0 on the 5 point Likert scale (Burden of arthritis symptoms: very much, much, moderate, little, none)

-Duration of response: time lapsed between reaching good response (positive change of at least 2 points) and consecutive loss of response defined as an ensuing negative change of at least 2 points on the 5 point Likert scale

-Time to good response (at least two points on the 5 point Likerts scale on at least two consecutive weeks)

-Asessment of arthritis activity by the trial physician on a 5 point Likert scale (very active, active, moderately active, slightly active, no activity)

-VAS pain at t = 0 and t = 12 weeks

-Change of Range of Motion (ROM) on physical examination, as determined by the trial physician on T=0 and T=12 weeks, measured in degrees with a protractor

-Change of swelling on physical examination, as determined by the trial physician on T=0 and T=12 weeks. Swelling will be measured as *yes* or *no*. Doubtful or little swelling will be scored as *no*.

-Change in patients health status by making use of The Western Ontario McMaster Universities Osteoarthritis index (WOMAC) at t = 0 and t = 12 weeks.

-Corticosteroid receptor measurements at t=12 in serum (10 ml of whole blood)

Study description

Background summary

Injections of corticosteroids are widely practised in rheumatology. Corticosteroid injections with long-lasting crystalline suspensions (depot formulations) have been used to treat arthritis and other painful musculoskeletal conditions since the 1950s. Their continuing use can be attributed to their safety record and the prompt, often substantial relief that they can provide patients. Different kinds of corticosteroids are used for local injection. Among the Dutch rheumatologists the most frequently used local corticosteroid is triamcinoloneacetonide (66%). Although local corticosteroid injections are widely practised, there are only few studies published in relationship with the response in pain relief and duration of pain relief on therapy. Factors predicting the response in pain relief of local corticosteroid injections are therefore largely unknown. Guidelines in dosage of local corticosteroids in different joints are lacking. A clinical dose-effect relationship has not yet been properly studied. The dosage being administered is currently determined by clinical tradition. Recent study among Dutch rheumatologists shows that different rheumatologists inject different amounts of different corticosteroids in joints. The dosages corticosteroid that are given in joints can differ between rheumatologists up to 100%. A comparison between the dosage of the corticosteroids and responses should be investigated to optimalize treatment in pain relief and duration of pain relief by injection with local corticosteroid.

A higher concentration of local corticosteroid could be related with a greater relief of symptoms in pain. A higher amount of drug in the target compartment

should lead to a prolonged local effect. In this study a comparison is being made between the response in relief of symptoms among patients with a conventional dosage (conventional dosage based on recent study) and a double dose of triamcinolone, with the overall question: does a higher dose of triamcinolone give better effect both measured in response in symptomatic relief and duration of pain relief? In theory a higher concentration of local corticosteroid could be more effective.

For patients with arthritis who fail to gain adequate relief from oral medications and non-pharmacological treatments, intra-articular corticosteroid injections are one of the few alternative nonsurgical adjunctive therapies available.2-5 Intra-articular corticosteroid injections have demonstrated an excellent safety record over many years and are described by the American College of Rheumatology (ACR) as *safe and effective when administered by an experienced physician.*5 As with any pharmacologic agent, however, corticosteroids do have side effects in general, such as systemic effects and flushing. These side-effects can be minimised when steroids are administered locally as an injection in the treatment of arthritis.

Study objective

To determine whether doubling the dose of corticosteroid injections in the treatment of arthritis in knee joints is more effective in the relief of symptoms as measured by change in the assessment of arthritis burden by the patient on a Likert 5-point scale, both in number of responding patients and in duration of response.

Study design

Double-blinded randomized trial

Intervention

none

Study burden and risks

Risks of participating is negligible as the dosage of local corticosteroids is currently practised as determined in recent study and as is also investigated as shown in investigated brochure (see references). Risk of premature termination of the study is therefore negligible. Subjects will be contacted at least within 28 days after study discharge/withdrawal for safety follow-up purposes

Contacts

Public
Ziekenhuisgroep Twente

boerhaavelaan 63
7555 BB
NL
Scientific
Ziekenhuisgroep Twente

boerhaavelaan 63
7555 BB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

•Arthritis patients, RA or other causes of chronic arthritis (not osteoarthritis and not gout) with an indication for local injection with corticosteroid due to active arthritis in knee joint.
•Patients should have stable anti-arthritic co-medication, no changes will be made during the trial.
•Patients need to score at least *matig* at a 5-point Likert scale at the initial questionnaire at t = 0 otherwise no significant difference can be measured.

Exclusion criteria

•Contraindication for local injection with corticosteroid (infection, relevant skin lesion, uncontrolled diabetes mellitus)

•Chronic (>3 months) or current use of more than 10mg prednisolone or equivalent daily.
•No informed consent.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2010
Enrollment:	94
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Kenacort A-40
Generic name:	Triamcinolone acetonide 40mg/ml
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	21-04-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
EudraCT	EUCTR2009-018187-10-NL
CCMO	NL31058.044.10