Double Dose Treatment: Corticosteroid injection therapy in arthritis.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21189

Source
NTR

Brief title
DoDo

Health condition

triamcinolon
triamcinolone
arthritis
RA
kenacort

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Zilvermeeuw 1,
7609 PP Almelo
+31(0)546 693 693
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Percentage of patients with sustained good response.

Secondary outcome

1. Percentage 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);

2. Duration of response: Time lapsed between reaching good response;

3. Time to good response;

4. Asessment of arthritis activity by the trial physician;

5. VAS pain at t = 0 and t = 12 weeks;

6. Change of Range of Motion (ROM) on physical examination;

7. Change of swelling on physical examination, as determined by the trial physician on T=0 and T=12 weeks;

8. Change in patients health status.

Study description

Background summary

Injections of corticosteroids are widely practised in rheumatology. Different kinds of corticosteroids are being used for local injection. Although local corticosteroid injections are widely practised, there are only few studies published in relationship with the response on the therapy. Factors predicting the response in pain relief of local corticosteroid injections are therefore largely unknown. A clinical dose-effect relationship has not yet been properly studied. The amount of drug being dosed is currently determined by clinical tradition.

Study objective

To determine whether doubling the dose of corticosteroid injections in the treatment of arthritis in knee joints is more effective, both in number of responding patients and in duration of response (pain relief).

Study design

t = 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 weeks.

Intervention

Patients will receive 40 or 80 mg triamcinolone (Kenacort) to determine whether doubling the dose of corticosteroid injections in the treatment of arthritis in knee joint is more effective in the relief of symptoms.

Contacts

Public
Zilvermeeuw 1
J.W. Popma
Almelo 7609 PP
The Netherlands
+31 (0)546 695666
Scientific
Zilvermeeuw 1
J.W. Popma
Almelo 7609 PP
The Netherlands
+31 (0)546 695666

Eligibility criteria

Inclusion criteria

1. 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;

2. Patients should have stable anti-arthritic co-medication.

Exclusion criteria

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

2. Chronic (>3 months) or current use of more than 10mg prednisolone or equivalent daily;

3. No informed consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2010
Enrollment:	94
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-04-2010
Application type:	First submission

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
NTR-new	NL2174
NTR-old	NTR2298
Other	METC Enschede : P10-10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A