A randomised placebo-controlled trial in the management of ostheoarthritis of the temporomandibular joint for arthrocentesis with additional dexamethasone versus arthrocentesis alone.

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This study examines if there are therapeutic benefits over injecting dexamethason into the temporomandibular joint after arthrocentesis with patients with ostheoarthritis.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON30205

Source
ToetsingOnline

Brief title
The efficacy of additional dexamethason for treatment of ostheoarthritis.

Condition

- Bone and joint therapeutic procedures

Synonym
joint pain, ostheoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: In aanvraag

Intervention

Keyword: Arthrocentesis, Dexamethason, Ostheoarthritis, Temporomandibular

Outcome measures

Primary outcome

Pain.

The difference in pain before and after the treatment will be measured using the Visual Analog Scale (0 100 mm).

In the experimental group the treatment is considered succesful when 90 percent of the patiënts achieve a 30 percent reduction in pain with jaw movement on the VAS scale .
In the control group the treatment is considered succesful when 50 percent of the patiënts achieve a 30 percent reduction in pain with jaw movement on the VAS scale.

Secondary outcome

Mandibular Function Impairment Questionnaire (MFIQ).

Difference in units before and after the treatment on the MFIQ scale.

The treatment is considered succesfull if there is a minimum reduction of 13 units on the MFIQ scale.

The maximum mouth opening (mm) is measured at each folluw up.

Study description

Background summary

Arthrocentesis is described as a intra articular lavage of the temporomandibular joint wiith a saline solution. Nowadays arthrocentesis is used as a treatment for degenerative or reumathoid arthritis, capsulitis, movement impairment, pain, function impairment.
In some cases, corticosteroïds are used as additive therapy after the isotonic saline solution. Corticosteroids modify the vascular respons against an infection, inhibit destructive enzymes en slow down the actions of inflammatory agents. Intra-articular injections are meant to maximise the local defense mechanism and minimise the negative systemic effects. Corticosteroïden, like dexamethasone, react with nucleair steroïd receptors to control the synthesis of mRNA and proteins. This results in change in T- en B- cel function, changes in amount of cytokines and enzymes, inhibition of fosfolipase A2, resulting in a reduction of proinflammatory products of arachidonic acid.
The use of corticosteroid remains controversial because of the adverse effects. Probably, only a short term reduction in pain is achieved, whereas no long term reduction is likely to occur. Systemic adverse effect are seldom with the use of locally applied corticosteroïds. A few rapports claim that intra-articular administered corticosteroids could lead to destruction cartilage, infection and worsening of the present disease.
Possibly, the additional administering of corticosteroids in artrocentese is not beneficial, since these products may only cause an initial reduction of the pain and not lead to curation of the disease and may even worsen it.

Study objective

This study examines if there are therapeutic benefits over injecting dexamethason into the temporomandibular joint after arthrocentesis with patients with ostheoarthritis.

Study design

A randomised double-blind placebo-controlled trial.

Intervention

Group A receives arthrocentesis, plus lavage with 1,0 ml (concentration 20 mg/ml) dexamethason.

Group B receives arthrocentesis, plus lavage with 1.0 ml placebo solution.

Study burden and risks

There is no extra risk involved for the patients, since the therapy under research is the standard therapy. After arthrocentesis there is always an extra lavage of the joint with dexamethason.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Initial therapy not succesful; splint-therapy, soft food diet, NSAID's, physiotherapy .
Local anesthetics gives pain relief.

Exclusion criteria

Ankylosis
Rheumatoid arthritis
Underwent open jaw surgery in the past
Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2006
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Dexamethasone
Generic name:	Dexamethasone
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2006-005769-20-NL
CCMO	NL14439.042.06