effect of the combination of green lipped mussel, curcumin and ribus nigrum (supplement Synofit) on quality of life and pain in patients with osteoarthritis of the knee

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measuring the efficicy of the combination of green lipped mussel, curcumin and ribus nigrum (supplement Synofit) on quality of life and pain in patients with osteoarthritis of the knee

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

Summary

ID

NL-OMON39393

Source
ToetsingOnline

Brief title
Effect of Synofit in patients with osteoarthritis of the knee

Condition

- Joint disorders

Synonym
arthritis of the knee, gonarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisvoorzieningen Gelderse Vallei
Source(s) of monetary or material Support: Synofit Bv levert product. Maatschap orthopedie en ZGV nemen kosten poliklinische bezoek op zich.,Synofit Europe BV

Intervention

Keyword: green lipped mussel, osteoarthritis, quality of life

Outcome measures

Primary outcome

during the first consultation and at 6, 12 and 18 weeks, the pain scores by the

VAS-scale and quality of life by the KOOS-score are taken. Another outcome is

extra pain medication within one of the study periods of suppletion.

Secondary outcome

side-effects

compliance

Study description

Background summary

Synofit as supplement is succesfully used in equestrianism for many years (1). Ingredients of Synofit are the greenlipped mussel, curcumin and ribus nigrem. Literature describes an inhibited efficacy on inflammation of these ingredients. Inflammation always excists in osteoarthritis. The suplementation of Synofit is never described in literature.
In our practice we recommand Synofit beside the standard treatment in patients with osteoarhtritis of the knee. In our view Synofit is a relief for patients with an contra-indication for NSAIDs, for example patients using aspirin or anticoagulants.

Study objective

measuring the efficicy of the combination of green lipped mussel, curcumin and ribus nigrum (supplement Synofit) on quality of life and pain in patients with

osteoarthritis of the knee

Study design

randomized placebo controlled crossover study

Population
62 patients with osteoarthritis of the knee, seen in a first consultation in our clinic

Inclusion
- patients with clinical and radiological osteoarthritis of the knee (uni-and bilateral)
- voluntary participation of patient

Exclusion
- patients with arthritis of the knee with an operative indication
- co-mborbidity: rheumatoid arthritis, polyarthritis
- patient who use medication as: methotrexate and systemic corticosteroids
- arthritis of the hip at the same side (referred pain)
- patients who use analgetica stronger than NSAIDs (f.e. Tramadol, opioids)
- pregnancy
- allergy or sensitivity for ingredients of Synofit
- patient who use Synofit before

complementary investigation
an X-ray of the knee
no further investigation

Intervention
first 6 weeks of placebo or synofit supplemantation after that a wash-out interval of 6 weeks followed by again 6 weeks of either placebo or synofit

Outcome
during the first consultation and at 6, 12 and 18 weeks, the pain scores by the VAS-scale and quality of life by the KOOS-score are taken

Intervention

first 6 weeks of placebo or combination of green lipped mussel, curcumin and ribus nigrum (supplement Synofit) supplemantation after that a wash-out interval of 6 weeks followed by 6 weeks of either placebo or combination of green lipped mussel, curcumin and ribus nigrum (supplement Synofit)

Study burden and risks

Participants recieve information about the study and can abstain of participation at any time during the study.
Patients with an allergy or sensitivity for one of the ingredients of the combination of green lipped mussel, curcumin and ribus nigrum (supplement Synofit) will be excluded.

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

- patients with clinical and radiological osteoarthritis of the knee (uni-and bilateral)
- voluntary participation

Exclusion criteria

- patients with arthritis of the knee with an operation indication
- comborbidity: rheumatoid arthritis, polyarthritis
- patient who use medication as: methotrexate and systemic corticosteroids
- arthritis of the hip at the same side (referred pain)
- patients who use analgetica stronger than NSAIDs (f.e. Tramadol, Opioids)
- pregnancy
- allergic or sensitivity for ingredients of Synofit
- patient who use Synofit before

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2013
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO

Date:	09-08-2013
Application type:	First submission

Review commission: METC Wageningen Universiteit (Wageningen)

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
CCMO	NL40936.081.12