Efficacy of eggshell membrane in osteoarthritis

No registrations found.

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

Summary

ID

NL-OMON25644

Source
NTR

Health condition

osteoarthritis

Sponsors and support

Primary sponsor: JLK Nutrition
Source(s) of monetary or material Support: DEPP

Intervention

Outcome measures

Primary outcome

Main study endpoint includes assessment of self-reported pain (0-10) on a Numerical Rating Scale (NRS pain) after 6 weeks

Secondary outcome

Secondary endpoints include assessment of self-reported pain (0-10) on a Numerical Rating Scale (NRS pain) after 12 weeks, as well as self-reported stiffness and function/health through Knee injury and Osteoarthritis Outcome Scores (KOOS) on days 42 and 84.

Study description

Background summary

Poor joint health is a significant burden to society. Millions of people suffer from a kind of joint related disorder or disease, most often osteoarthritis. In those cases the cartilage in the joint is affected through inflammation, and/or inadequate balance of cartilage build-up versus degradation. It is hypothesized that chicken eggshell membrane is effective in the regeneration of cartilage and/or immunomodulation (oral tolerance), and as such positively affects pain and stiffness in joints commonly affected in arthritis. The main objective is to demonstrate a significant improvement in self-reported pain after 6 weeks of consumption of eggshell membrane in a typical population. Secondary, stiffness and performance indices will be assessed. The study will be set-up as a randomized, double-blind, placebo controlled intervention trial. One-hundred and fifty (150) volunteers, men and women, 40-75 years old diagnosed who meet all of the inclusion criteria and none of the exclusion criteria will be included in the study. For a period of 12 weeks one group receives a daily capsule containing eggshell membrane, and the other group daily receives a placebo capsule.

Study objective

It is hypothesized that chicken eggshell membrane is effective in the regeneration of cartilage and/or immunomodulation (oral tolerance), and as such positively affects pain and stiffness in joints commonly affected in arthritis

Study design

0,3,6,12 weeks

Intervention

For a period of 12 weeks one group receives a daily capsule containing eggshell membrane, and the other group daily receives a placebo capsule.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

• Age between 40-75

• NRS pain of 3 or more

• Diagnosed with osteoarthritis of the knee (confirmed by Health Care Professional)

• Able to understand, read, and write Dutch

• Daily access to e-mail and internet

• Non-smoking

• Signed informed consent

• Willing to comply with study procedures

Exclusion criteria

• NRS pain of 9 or 10

• Use of supplements aimed to target specifically osteoarthritis and/or rheumatoid arthritis (including glucosamine, chondroitin, collagen, MSM, green lip mussel, Boswelia extract or the-like) within 2 months prior to the start of the study

• Known allergy to eggs or egg products

• Pregnant or breastfeeding women

• Previously enrolment in a study to evaluate pain relief within the past 6 months or currently involved in any other research study involving an investigational product (drug, device, or biologic) or a new application of an approved product

Study design

Design

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

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	08-09-2018
Enrollment:	0
Type:	Unknown

Ethics review

Positive opinion

Date:	10-09-2018
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	NL7309

Register	ID
NTR-old	NTR7525
Other	METC (IRBN, Nijmegen) : ABR 64636

Study results