Efficacy of mildly processed natural eggshell membrane in the alleviation of joint pain associated with osteoarthritis

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

Summary

ID

NL-OMON46782

Source
ToetsingOnline

Brief title
Efficacy of eggshell membrane

Condition

- Joint disorders

Synonym
arthritis, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: DEPP BV
Source(s) of monetary or material Support: Ministerie van OC&W,Bedrijf

Intervention

Keyword: arthritis, efficacy, eggshell, membrane

Outcome measures

Primary outcome

Main study parameter is observed change in self-reported pain on a Numeric Rating Scale (NRS pain) after 6 weeks as a result of intervention both for product and placebo.

Secondary outcome

Secondary, pain after 12 weeks (NRS pain), and other self reported disease related outcomes after 6 and 12 weeks will be assessed through Knee injury and Osteoarthritis Outcome Scores (KOOS).

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.

Study objective

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 suffering from knee osteoarthritis. Secondary, stiffness and performance indices will be assessed.

Study design

The study will be set-up as a randomized, double-blind, placebo controlled

intervention trial.

Intervention

For a period of 12 weeks one group receives a daily capsule containing 300 mg of eggshell membrane, and the other group daily receives a placebo capsule.

Study burden and risks

Subjects are asked to fill in a short questionnaire prior to enrolment. During 84 days subjects will be asked to take either a placebo or product capsule once a day, and keep a simple daily diary. On a weekly basis, they will be asked to list NRS pain (0-10). On days 0, 10, 21, 42, and 84 they will fill-in the KOOS questionnaire. To our opinion, the burden and risks of participation in this study for physical or mental wellbeing are negligible.

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

Age between 40-75
NRS pain of 3 or more
Diagnosed with osteoarthritis of the knee (confirmed by Health Care Professional)

Exclusion criteria

Daily use of NSAIDs
Use of opiates
Use of supplements aimed to target specifically osteoarthritis and/or rheumatoid arthritis

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:	Recruitment stopped
Start date (anticipated):	08-09-2018
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	24-04-2018
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL64636.072.18