

Efficacy of eggshell membrane in osteoarthritis

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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

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25644

Bron

Nationaal Trial Register

Aandoening

osteoarthritis

Ondersteuning

Primaire sponsor: JLK Nutrition

Overige ondersteuning: DEPP

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

0,3,6,12 weeks

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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, Boswelvia 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

Onderzoekopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	08-09-2018
Aantal proefpersonen:	0
Type:	Onbekend

Ethische beoordeling

Positief advies	
Datum:	10-09-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7309

Register

NTR-old

Ander register

ID

NTR7525

METC (IRBN, Nijmegen) : ABR 64636

Resultaten