CoKnie

No registrations found.

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

Summary

ID

NL-OMON27720

Source
Nationaal Trial Register

Brief title
CoKnie

Health condition

Osteoarthritis patients in who total knee replacement is planned

Sponsors and support

Primary sponsor: Wageningen University & Research
Source(s) of monetary or material Support: Rousselot

Intervention

Outcome measures

Primary outcome

The primary objective is to investigate the difference between the two groups in change from baseline in Oxford Knee Scores at 6 weeks after the surgery.

Secondary outcome

Secondary objectives are to assess the difference between the two groups
in change from baseline in Oxford Knee Scores at 12 weeks after the surgery and at 6 months

after the surgery.

On pain VAS scores measured at hospital admission, 2 weeks post-surgery, and 6 weeks post-surgery.

On the amount and period of pain relieving therapies,
On inflammation in synovial fluid, muscle and knee function, functional tests and clinical outcome parameters.

Study description

Study design

6 weeks, 12 weeks and 6 months after surgery

Intervention

Daily supplementation of hydrolysed collagen (10g) or placebo (maltodextrin; 10g), for a period of 12 weeks. All supplements will be provided as flavoured powder drink products that can be dissolved in water.

Contacts

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Eligibility criteria

Inclusion criteria

Planned for total knee replacement therapy

> 18 years old and mentally competent

Exclusion criteria

Current use (latest use one week or less before inclusion) of supplements (like glucosamine, chondroitin, green-lipped mussel, curcumin or blackcurrant leaf).

Diagnosed with Rheumatoid Arthritis

Medical history of renal insufficiency (eGRF<60ml)

Daily use of high doses NSAIDs in the 14 days before inclusion: Defined as higher than maintenance dose in the “farmacotherapeutisch kompas”.

Vegetarians

Childbearing potential

Inability to perform the functional tests due to other impairments than the knee that is to be replaced
Use of systemic corticosteroids

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2017
Enrollment:	92
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42856
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6290
NTR-old	NTR6464
CCMO	NL58987.081.16
OMON	NL-OMON42856

Study results