The effect of hydrolysed COllagen (Peptan®) on pain, synovial inflammation and postoperative outcome in patients undergoing total KNee replacement therapy

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In this study we would like to investigate the effect of CP (Peptan®) on pain, synovial inflammation and functional and clinical outcome parameters in patients undergoing total knee replacement therapy.

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

Summary

ID

NL-OMON42856

Source
ToetsingOnline

Brief title
CoKnee

Condition

- Other condition
- Bone and joint therapeutic procedures

Synonym
damaged knee and knee replacement

Health condition

osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: bedrijf: Rousselot,Rousselot

Intervention

Keyword: hydrolysed collagen, knee arthroplasty, Oxford Knee Score

Outcome measures

Primary outcome

The primary objective is to investigate the effect of collagen peptides

(Peptan®) on pain and knee function in patients undergoing total knee

replacement therapy.

Secondary outcome

Secondary objectives are to assess the effect of collagen peptides (Peptan®)

on the amount and period of pain reducing therapies,

synovial inflammation, wound healing,

muscle and knee function, mobiliteit

clinical outcome parameters (e.g. PROMS) in patients undergoing total knee

arthroplasty

Study description

Background summary

Patients undergoing knee surgery often suffer from pain and discomfort during the days after surgery. Pain and discomfort can be influenced by inflammation in the knee and /or by decreased muscle function. Collagen peptides may reduce pain in patients and stabilize muscle function in patients, thereby improving

clinical outcome and well-being of patients.

Study objective

In this study we would like to investigate the effect of CP (Peptan®) on pain, synovial inflammation and functional and clinical outcome parameters in patients undergoing total knee replacement therapy.

Study design

This is a double-blind randomized placebo-controlled trial.

Intervention

To receive daily either Peptan® or placebo (maltodextrin) supplement for 12 weeks.

Study burden and risks

This study will provide more information about the clinical effects of Peptan® compared to placebo on pain and pain reducing therapies. This information is valuable since reduction in NSAIDs and other pain killers in this population would be worthwhile. No adverse effects of peptan® or placebo are expected. The study has been designed to blend as much as possible with standard clinical care.
Based on these considerations, to our opinion, the risks for the participants are negligible, and do not outweigh the scientific relevance of this study

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

• 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 anti-inflammatory supplements (like glucosamine, chondroitin, green-lipped mussel, curcumin or blackcurrant leaf).
• Diagnosed with Rheumatoid Arthritis
• Medical history of renal insufficiency
• Daily use of high doses NSAIDs in the 14 days before inclusion:
Defined as higher than maintenance dose (in the "farmacotherapeutisch kompas")
for example: acetylsalicylic acid > 4 g /day; diclofenac > 75 mg/day; naproxen > 500 mg/day; ibuprofen> 1600 mg /day; celecoxib >200 mg/day
Use of systemic corticosteroids
• Vegetarians
• Childbearing potential
• Inability to perform the functional tests due to other impairments than the knee that is to be replaced

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-06-2017
Enrollment:	92
Type:	Actual

Ethics review

Approved WMO

Date:	02-03-2017
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

ID: 27720
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL58987.081.16

Register	ID
OMON	NL-OMON27720

Study results

Date completed:	03-07-2020
Actual enrolment:	92