# Cost-effectiveness of viscosupplementation therapy for patients with osteoarthritis of the knee: a randomized clinical trial.

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1. Viscosupplementation therapy for patients with osteoarthritis of the knee is cost-effective for the dutch health care system; 2. Viscosupplementation therapy for patients with osteoarthritis of the knee has a clinical relevant effect competed to...

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON26016

**Bron**
NTR

**Verkorte titel**
VISK study

**Aandoening**

osteoarthritis, knee; hyaluronic acid, cost-effectiveness,

### Ondersteuning

**Primaire sponsor:** Erasmus MC
Department of Orthopedics
J.A.N Verhaar, PhD MD, Head of the department
**Overige ondersteuning:** ZonMW

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Cost-effectiveness of 3 weekly intra-articular injections with a HA polymer added to usual care.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Assessment of cost-effectiveness and efectiveness of 3 weekly intra-articular injections with a HA polymer added to usual care in patients with clinical knee osteoartritis.

### Doel van het onderzoek

1. Viscosupplementation therapy for patients with osteoarthritis of the knee is cost-effective for the dutch health care system;

2. Viscosupplementation therapy for patients with osteoarthritis of the knee has a clinical relevant effect competed to usual treatment.

### Onderzoeksopzet

6 wk, 3, 6, 9, 12 mnth

### Onderzoeksproduct en/of interventie

Intra-articular injection with a high molecular weight chemically crosslinked hyaluronan polymer of avian origin (HA-polymer) will be given in total three times with a time interval of one week between injections (48 mg hyaluronate derivate per series), provided by a trained orthopedic surgeon according to a standardized protocol. This treatment with Hylan G-F 20 is added to the usual care treatment.

# Contactpersonen

## Publiek

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Knee pain needs to be present longer than 3 months;

2. Severity of the knee pain needs to be more than 2 mm on a VAS score;

3. Radiographic signs of knee OA needs to be present defined by a Kellgren & Lawrence score of grade 1 to 3.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Viscosupplementation in the target knee within the last year;

2. Glucocorticoid or steroid injection into the target knee within the last three months;

3. Intra-articular procedure (arthroscopy (< 6 months), lavage, tibial osteotomy) within the last year;

4. History of synovectomy;

5. Knee surgery scheduled within the next 9 months;

6. Dermatologic disorders or skin infection in proximity to the study knee;

7. Pregnant or planning to be pregnant or lactating females;

8. Poor general health status or specific condition that would interfere with functional assessments (bed ridden patients or patients in wheelchair or who are unable to walk 50 steps unaided);

9. Inflammatory arthritis;

10. Varus or valgus deformity > 12 degrees;

11. Chondrocalcinosis;

12. Presence of hip OA severe enough to affect the evaluation of function;

13. Receiving regular analgesic therapy for reasons other than painful OA of the knee;

14. Chronic use of daily (oral) steroid therapy;

15. Alcoholism;

16. Patients from whom it is not sure that they will be able to attend the follow-up measurements;

17. Insufficient command of the Dutch language, spoken and/or written.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-04-2009 |
| Aantal proefpersonen: | 154 |

| | |
|---|---|
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 03-03-2009 |
| 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 | NL1572 |
| NTR-old | NTR1651 |
| Ander register | MEC Erasmus MC : 2008-267 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

## Resultaten

**Samenvatting resultaten**
N/A