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

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To assess whether there is (cost) effectiveness over a period of 1 year of additive intra-articular injections with a high molecular HA derivate in patients with OA of the knee.

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

## Summary

### ID

NL-OMON32486

**Source**
ToetsingOnline

**Brief title**
Cost-effectiveness of hyaluronan injections for knee osteoarthritis

### Condition

- Joint disorders

**Synonym**
"arthrosis", "multifactoriel chronic joint disease"

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Zon Mw doelmatigheid programma kosten-

effectiviteit

## Intervention

**Keyword:** Cost-effectiveness, knee, osteoarthritis, viscosupplementation

## Outcome measures

### Primary outcome

Primary outcome is the difference in % of responders (improvement of ³ 20% in at least 2 of the 3 domains; pain, function, patient*s global assessment) after 12 months of follow-up.

### Secondary outcome

Difference in primary outcome parameter after 6 weeks, 3 and 6 months, in pain severity, KOOS, and quality of life (EQ5D) after 6 weeks, 3, 6 and 12 months. Also difference in side effects, medical consumption and costs (visits to health care providers and consumptions of prescription or over the counter medication), absence from work or decreased productivity at work, and patient costs to be able to do cost-effectiveness analysis will be assessed.

# Study description

### Background summary

Osteoarthritis (OA) is the most frequent chronic joint disease causing pain and disability of especially the knee. The usual choice of initial therapy in patients with clinical knee OA is pain relief by Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), if necessary combined with physical therapy. Another treatment option in patients with clinical knee OA is viscosupplementation (VS), which is reported by a Cochrane review to show good clinical results on pain, function and patient global assessment even in the long-term. Because of the lack of evidence of the cost-effectiveness of high molecular HA products in the Netherlands, the use of HA is very limited which

may result in higher total costs of treatment than necessary.

### Study objective

To assess whether there is (cost) effectiveness over a period of 1 year of additive intra-articular injections with a high molecular HA derivate in patients with OA of the knee.

### Study design

Open-labeled randomized clinical trial.

### Intervention

Intervention group; 3 injections with a high molecular HA derivate added to the usual care treatment (UC), the control group; UC (exercise therapy and pain medication).

### Study burden and risks

The measurements needed for the data collection of the present study consist of a standard X ray of the knee at baseline and questionnaires (30 minutes per time). These measurements are standard care in case of patients with knee OA. Only local reactions have been reported (transient and mild).

## 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

knee pain needs to be present longer than 3 months, severity of the knee pain needs to be more than 2 mm on a VAS score, and radiographic signs of knee OA needs to be present, defined by a Kellgren & Lawrence score of grade 1 to 3.

### Exclusion criteria

viscosupplementation in the target knee within the last year, glucocorticoid or steroid injection into the target knee within the last three months, intra-articular procedure (arthroscopy (< 6 months), lavage, tibial osteotomy) within the last year, history of synovectomy, knee surgery scheduled within the next 9 months, dermatologic disorders or skin infection in proximity to the study knee, pregnant or planning to be pregnant or lactating females, 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), inflammatory arthritis, varus or valgus deformity > 12 degrees, chondrocalcinosis, presence of hip OA severe enough to affect the evaluation of function, receiving regular analgesic therapy for reasons other than painful OA of the knee, chronic use of daily (oral) steroid therapy, alcoholism, patients from whom it is not sure that they will be able to attend the follow-up measurements, insufficient command of the Dutch language, spoken and/or written.

## Study design

### Design

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| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Parallel |

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| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-04-2009 |
| Enrollment: | 154 |
| Type: | Actual |

### Medical products/devices used

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| Product type: | Medicine |
| Brand name: | synvisc |
| Generic name: | Hylan G-F 20 |
| Registration: | Yes - NL intended use |

## Ethics review

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| Approved WMO Date: | 19-09-2008 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

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| Approved WMO Date: | 24-11-2008 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## 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 |
|---|---|
| EudraCT | EUCTR2008-005814-28-NL |
| CCMO | NL24430.078.08 |