

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

No registrations found.

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

Summary

ID

NL-OMON26016

Source

NTR

Brief title

VISK study

Health condition

osteoarthritis, knee; hyaluronic acid, cost-effectiveness,

Sponsors and support

Primary sponsor: Erasmus MC

Department of Orthopedics

J.A.N Verhaar, PhD MD, Head of the department

Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Effectiveness of 3 weekly intra-articular injections with HA polymer added to usual care. Subanalysis will be performed for severity of radiographic OA (Kellgren & Lawrence grade 1 and 2 versus grade 3).

Study description

Background summary

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

Study objective

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 compared to usual treatment.

Study design

6 wk, 3, 6, 9, 12 mnth

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2009
Enrollment:	154
Type:	Anticipated

Ethics review

Positive opinion

Date: 03-03-2009

Application type: First submission

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
NTR-new	NL1572
NTR-old	NTR1651
Other	MEC Erasmus MC : 2008-267
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A