

# The 10-year follow-up of the ESCAPE trial: Do patients with a non-obstructive meniscal tear develop more knee osteoarthritis after knee surgery or after exercise therapy?

Published: 19-01-2024

Last updated: 07-04-2024

To compare the degree of osteoarthritis in the knee after 10 years, in patients with non-obstructive meniscal tear, between meniscal surgery and exercise therapy treatment.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON56561

### Source

ToetsingOnline

### Brief title

ESCAPE 10 year follow-up

### Condition

- Joint disorders
- Bone and joint therapeutic procedures

### Synonym

Arthritis, joint wear

### Research involving

Human

## Sponsors and support

**Primary sponsor:** OLVG

**Source(s) of monetary or material Support:** Stichting Wetenschappelijk Onderzoek OLVG

## Intervention

**Keyword:** Exercise therapy, Meniscal tear, Osteoarthritis, Surgery

## Outcome measures

### Primary outcome

The main study outcome will be the progression of osteoarthritis scored according to the MOAKS score. The MOAKS score is a new semi-quantitative scoring tool to quantify OA status based on MRI images. The degree of knee osteoarthritis is also assessed through X-ray images, using the Kellgren and Lawrence (KL) grading scale which evaluates knee osteoarthritis at 5 different levels, ranging from 0 (no osteoarthritis) to 4 (severe knee osteoarthritis). Furthermore, the progression of OA is also measured using the Osteoarthritis Research Society International (OARSI) Atlas sum score, ranging from 0 to 18 based on 6 items.

### Secondary outcome

The secondary outcome measures of the study include knee function, pain, and quality of life, assessed through digital questionnaires (Patient-Reported Outcome Measures or PROMs). The following questionnaires will be utilized:

- KOOS (Knee injury and Osteoarthritis Outcome Score)
- EQ-5D (EuroQol-5 Dimension)
- IKDC (International Knee Documentation Committee)

## Study description

### Background summary

Knee osteoarthritis (OA) is a condition with a significant burden on both the patient and society. Randomized clinical trials have shown that arthroscopic partial meniscectomy is not beneficial in terms of physical functionality compared to exercise therapy in the first two years. There are indications that meniscal surgery is one of the etiological factors for the accelerated development of OA in the operated knee. However, this has not been convincingly demonstrated in a long term RCT. We would like to further investigate the progression of OA at a minimum of 10 years follow-up.

### Study objective

To compare the degree of osteoarthritis in the knee after 10 years, in patients with non-obstructive meniscal tear, between meniscal surgery and exercise therapy treatment.

### Study design

The research is a follow-up to the ESCAPE trial, where patients aged 45-70 with a non-obstructive meniscus tear were randomized to undergo either surgery or physiotherapy. In this subsequent study, the progression of osteoarthritis in the affected knee is examined ten years after treatment. This is assessed using MRI and X-ray images, which are compared to the baseline photos. All patients reach the ten year point after their treatment between juli 2023 and november 2025.

### Study burden and risks

The burden consists, on the one hand, of a one-time hospital visit where MRI and X-rays will be taken (approximately 60 minutes). The latter carries a small risk of harm due to the use of radiation, but is not considered dangerous. In addition, the participant will complete a one-time set of questionnaires (maximum 30 minutes). The total time that a patient is burdened during the study is approximately 90 minutes.

Particapant benefit from the study in getting a evaluation of their current health condition. Patients are able to see the results in their "MijnOLVG" page.

## Contacts

### **Public**

OLVG

Oosterpark 9  
Amsterdam 1091AC  
NL

### **Scientific**

OLVG

Oosterpark 9  
Amsterdam 1091AC  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patients diagnosed with a non-obstructive meniscal tear 10 years ago who participated in the ESCAPE trial.

### Exclusion criteria

Not providing informed consent or indicated not to be approached for follow-up research.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-02-2024

Enrollment: 130

Type: Anticipated

### Medical products/devices used

Registration: No

## Ethics review

Approved WMO

Date: 19-01-2024

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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
CCMO	NL84754.100.23