Walking ALteration for Knee osteoarthritis.

No registrations found.

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

Summary

ID

NL-OMON26376

Source
Nationaal Trial Register

Brief title
The WALK Study

Health condition

Knee Osteoarthritis
Knee extension deficit
Conservative treatment
Physiotherapy protocol

Sponsors and support

Primary sponsor: Raad van bestuur Máxima Medisch Centrum
Source(s) of monetary or material Support: Máxima Medisch Centrum

Intervention

Outcome measures

Primary outcome

Between group difference in change in pain score of the KOOS between baseline and 3 months follow-up.

Secondary outcome

- Comparison of percentage of responders according to the OMERACT/OARSI set of responder criteria, during 12 months follow up, in the control and index group. To measure pain and function, the Number Rating Scale for knee pain (NRS) and KOOS physical function will be used, while for global assessment a Likert scale will be used. These outcomes will be assessed during the first 3 months of the study: weekly, and thereafter: at 6, 9 and 12 months after baseline measurement.

After 3 and 12 months of follow-up groups will be compared concerning change since baseline of:

- Number Rating Scale for knee pain (NRS)

- EQ-5D; Intermittent and Constant OsteoArthritis Pain (ICOAP);

- treatment failure (TKA during follow-up; or in “need for TKA” OARSI-criteria after 12 months; or other surgical interventions of the knee during follow-up (osteotomy of high tibia or low femur; arthroscopic intervention; UKA));

- Range of motion of the knee (ROM)

- gait parameters as assessed by gait analyses

- medication use.

To get more insight in which specific patients will respond on the current intervention also the HADS, Central Sensitization Inventory, pain drawing form and pain cognition list will be evaluated.

Study description

Background summary

Osteoarthritis (OA) of the knee is associated with changes in gait pattern. Our hypothesis is that adaptation of the gait pattern through gait retraining can relieve the symptoms in knee OA. A RCT will be performed to compare the effectiveness of the WALK gait retraining program, compared to a standardised treatment protocol based on the KNGF guidelines, in patients with clinical symptoms of mild to moderate knee OA and a knee extension deficit. Main study endpoints is between group difference in change in pain and function score

between baseline and 3 months follow-up. Secondary outcome parameters are gait analysis and functional outcome.

Study objective

The WALK gait retraining program is more effective to treat patients with symptomatic mild to moderate knee OA and an extension deficit, compared to a standardised treatment protocol based on the KNGF (royal Dutch association of physiotherapists) guidelines.

Study design

Baseline, during the first 3 months of the study: weekly, at 6, 9 and 12 month follow-up.

Intervention

Patients will be randomized in a group

(a) control group: physiotherapy with a standardised treatment protocol based on the KNGF (royal Dutch association of physiotherapists) guidelines.

(b) index group: WALK gait retraining program.

Contacts

Public
J.J. Tolk
Eindhoven
The Netherlands
Scientific
J.J. Tolk
Eindhoven
The Netherlands

Eligibility criteria

Inclusion criteria

Symptomatic knee OA according to the clinical ACR criteria.

Radiographic OA, according to Kellgren and Lawrence grade 1, 2 or 3

Flexion contracture of 5 degrees or more.

Exclusion criteria

- Medial or lateral instability of the knee,

- Symptomatic bilateral knee OA

- Intra-articular injection of the knee, in the previous 3 months

- Previous peri-articular osteotomy of the affected knee

- Symptomatic OA of hip or ankle

- Co morbidity which disables the function of the lower extremity

- Rheumatoid Arthritis or other inflammatory joint disease

- Physical therapy for current complaints during last 3 months

- Insufficient command of the Dutch language

- Legally incompetent adults

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):	01-10-2018
Enrollment:	144

Type:	Anticipated

Ethics review

Positive opinion

Date:	03-03-2017
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	NL6810
NTR-old	NTR6996
Other	:

Study results