Efficacy of MRI in primary care for patients with knee complaints due to trauma.

No registrations found.

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

Summary

ID

NL-OMON25720

Source
Nationaal Trial Register

Brief title
TACKLE trial

Health condition

Traumatic knee complaints, MRI, Primary care, Cost-effectiveness, Efficacy, Randomized controlled trial, Noninferiority design

Sponsors and support

Primary sponsor: Erasmus MC, Erasmus University Medical Center, Department General practice (PO Box 2040, 3000 CA Rotterdam, Netherlands).

- Leiden University Medical Center (LUMC), Department Radiology (PO Box 9600, 2300 RC Leiden, Netherlands).
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

1. Lysholm Scale to measure patients' knee related self reported daily function. The score consists of 8 different items on a 100-point scale with 25 points each attributed to instability and pain, including an activity-grading scale;

2. PROductivity and DISease Questionnaire (PRODISQ) to measure the productivity costs (due to absence of work and reduced productivity in (un)paid work and the questionnaire for Costs (modified TiC-P) to measure direct medical costs of MRI, medical consumption (e.g. other additional diagnostics, referrals, medication, consults, arthroscopy, surgery, physical therapy, aids);

3. EuroQol 5-D self-reported questionnaire (EQ-5D) to measure patients' quality of life on five dimensions; mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

Secondary outcome

1. The Knee Injury and Osteoarthritis Outcome Score (KOOS) to measure patients' knee function;

2. 11-point numeric rating scale to capture the severity of knee pain (0=no pain and 10=unbearable pain);

3. The Global Perceived Effect (GPE) to measure patients' perceived recovery and satisfaction of the patient.

Study description

Background summary

Rationale:

General practitioners are regularly consulted by patients with traumatic knee complaints. The Dutch clinical guideline 'traumatic knee complaints' for general practitioners at present does not recommend referral to MRI because lack of evidence. Direct referral to MRI might be a valuable tool for general practitioners in making appropriate and informed decisions, depending on whether it improves patient outcomes, reduces costs and affects subsequent diagnosis and management.

Objective:

What is the cost-effectiveness of referral to MRI by the general practitioner compared to usual care in patients with persistent traumatic knee complaints.

Study design:

A multi-centre, open labeled randomized controlled noninferiority trial in combination with a concurrent observational cohort study.

Study population:

Patients (aged between 18 and 45 years) with traumatic knee complaints will be eligible if they have consulted their general practitioner and and report persistent knee complaints till 6 months.

Intervention:

Participating patients will be randomized into two groups:

1. MRI group; the patients will be referred for MRI of the knee by the general practitioner, or;

2. Usual care group; the patients will receive care conform the Dutch general practitioners' clinical guideline and will not receive an MRI referral by the general practitioner.

Main study parameters/endpoints:

The primary outcomes are self reported knee related daily function (Lysholm), health care and productivity costs (PRODISQ/TIC-P), and quality of life (EuroQol) over a 12 months follow-up period (measured at 0,1.5, 3, 6, 9, 12 months).

Secondary outcomes are patient related health gain measured with function (KOOS), severity of knee pain (NRS) and perceived recovery and satisfaction with management by patient and general practitioner.

Study objective

Over a period of 12 months follow-up:

1. What is the cost-effectiveness of MRI referral by the general practitioner compared to usual care in patients with persistent traumatic knee complaints?

2. Is MRI referral by the general practitioner noninferior compared to usual care in patients with persistent traumatic knee complaints regarding self reported knee related daily function?

Study design

All participating patients will fill in the questionnaires at baseline and at 1.5, 3, 6, 9 and 12 months follow-up.

Intervention

Group 1; the MRI group:

Patients will be referred for MRI scan (1.5 T) of the affected knee at a participating MRI center within 4 weeks after referral.

Group 2; the usual care group:

These patients will be managed conform the care recommended by the Dutch clinical guideline ‘traumatic knee complaints’.

Contacts

Public
Leiden University Medical Center, Department of Radiology, C-2-S, 2300RC Leiden, The Netherlands
Monique Reijnierse
Rotterdam 3000 CA
The Netherlands
+31 715262052
Scientific
Leiden University Medical Center, Department of Radiology, C-2-S, 2300RC Leiden, The Netherlands
Monique Reijnierse
Rotterdam 3000 CA
The Netherlands
+31 715262052

Eligibility criteria

Inclusion criteria

Patients will be eligible for inclusion if they:

1. (Re)consulted their general practitioner with knee complaints (pain and/or disability of at least 4 weeks) due to trauma or sudden onset in the preceding six months, and;

2. Are aged 18 to 45 years.
3. Pain and/or disability

Exclusion criteria

Patients will be excluded if:

1. There is an indication for direct referral to an orthopaedic surgeon such as suspicion of fracture and/or an acute locked knee;

2. The knee complaints due to trauma are already treated in secondary care;

3. The patient is already known with osteoarthritis in the affected knee, other nontraumatic arthropathy, isolated patello-femoral joint pain or patella luxation;

4. There is a previous MRI examination within the same episode of knee complaints;

5. There is a previous surgical intervention on the same knee, and;

6. There are contra-indications for the use of MRI (claustrophobia, metal implants or a pacemaker).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-10-2012
Enrollment:	360
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-11-2012
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	NL3534
NTR-old	NTR3689
Other	METC Erasmus MC Rotterdam : 2012-190

Register	ID
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

1. Swart NM, van Oudenaarde K, Algra PR, Bindels PJ, van den Hout WB, Koes BW, Nelissen RGHH, Verhaar JAN, Bloem JL, Bierma-Zeinstra SMA, Reijnierse M, Luijsterburg PAJ. Efficacy of MRI in primary care for patients with knee complaints due to trauma: protocol of a randomized controlled non-inferiority trial (TACKLE trial). BMC Musculoskeletal Disordering. 2014; mar 3; 15:63.

2. van Oudenaarde K, Swart NM, Bierma-Zeinstra MSA, Algra PR, Bindels PJ, Nelissen RGHH, Verhaar JAN, Luijsterburg PAJ, Reijnierse M, van den Hout WB. General practitioners referring adults to MR imaging for knee pain: a randomized controlled trial to assess cost-effectiveness. Radiology 2018 Jul;288(1):170-176.

3. Van Oudenaarde K, Swart NM, Bloem JL, Bierma-Zeinstra SMA, Algra PR, Bindels PJE, et al. MRI-knie bij iedere patiënt met acuut knietrauma niet kosteneffectief. Huisarts Wet 2018;61:DOI: 10.1007/s12445-018-0267-0. Dit is een bewerkte vertaling met toestemming van Radiology 2018 Jul;288(1):170-176
https://www.henw.org/artikelen/mri-knie-bij-iedere-patient-met-acuut-knietrauma-niet-kosten effectief

Dissertation Kim van Oudenaarde, Leiden University November 22, 2018

https://openaccess.leidenuniv.nl/bitstream/handle/1887/67119/front.pdf?sequence=3

Dissertation Nynke Swart, Erasmus Medical Center October 15, 2019

https://epubs.ogc.nl/?epub=n.swart