

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25720

Bron

Nationaal Trial Register

Verkorte titel

TACKLE trial

Aandoening

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

Ondersteuning

Primaire 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).

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 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.

Doel van het onderzoek

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?

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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'.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd

Controle: Actieve controle groep

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 19-10-2012
Aantal proefpersonen: 360
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 07-11-2012
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3534
NTR-old	NTR3689
Ander register	METC Erasmus MC Rotterdam : 2012-190
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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, Reijnen 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 Disorders. 2014; mar 3; 15:63.

2. van Oudenaarde K, Swart NM, Bierma-Zeinstra MSA, Algra PR, Bindels PJ, Nelissen RGHH, Verhaar JAN, Luijsterburg PAJ, Reijnen 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>