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

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON41300

Source
ToetsingOnline

Brief title
TACKLE trial

Condition

- Tendon, ligament and cartilage disorders

Synonym
knee compaints, Knee injuries

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw;doelmatigheid ronde 2012

Intervention

Keyword: General Practitioner, Knee trauma, MRI, Primary care

Outcome measures

Primary outcome

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*, 3, 6, 9, 12 months).

Secondary outcome

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 description

Background summary

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 the efficacy is of an MRI in primary care for patients with traumatic knee complaints is still unknown. 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.

Study objective

What is the cost-effectiveness of referral to MRI compared to usual care by the general practitioner 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.

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.

Study burden and risks

There are no risks associated with participation. The only tests that are used are questionnaires, which will take about 30 minutes to fill in every 3 months. Altogether this will take the patient 3 hours over a period of 1 year. The questionnaires that are used are not associated with physical and physiological discomfort. There are no benefits associated with participation, because the efficacy is of an MRI in primary care for patients with traumatic knee complaints is still unknown.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients will be eligible for inclusion if they:
- (re)consulted their general practitioner with knee complaints (persistent pain and/or disability) due to trauma or sudden onset in the preceding six months and
- are aged 18 to 45 years.

Exclusion criteria

Patients will be excluded if:
- there is an indication for direct referral to an orthopaedic surgeon such as suspicion of fracture and/or an acute locked knee,
- the knee complaints due to trauma are already treated in secondary care,
- the patient is already known with osteoarthritis in the affected knee, other non- traumatic arthropathy, isolated patello-femoral joint pain or patella luxation,
- there is a previous MRI examination within the same episode of knee complaints,
- there is a previous surgical intervention on the same knee, and
- there are contra-indications for the use of MRI (claustrophobia, pregnancy, 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
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2012
Enrollment:	360
Type:	Actual

Ethics review

Approved WMO Date:	19-10-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-09-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-02-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL40296.078.12