Functional treatment versus immobilization for primary patella luxations: a prospective randomized trial

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Functional treatment with a brace and early physiotherapy will result in improved Kujala scores (reflecting better functional outcome with less pain) and SF-36 scores (reflecting higher quality of life) at 1 year compared with plaster immobilization...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON33151

Source
ToetsingOnline

Brief title
Pallux trial

Condition

- Muscle disorders
- Bone and joint therapeutic procedures

Synonym
patellar dislocation/ kneecap luxation

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Fondsen van ziekenhuis (WAC) zijn

aangeschreven

Intervention

Keyword: luxation, patella, plaster, treatment

Outcome measures

Primary outcome

- Functional outcome and pain, as measured by the Kujala score, one year after brace and plaster treatment in patients over 12 years of age, who sustained an acute traumatic patella luxation.

- Quality of life, as measured by the SF-36 score, one year after brace and plaster treatment.

Secondary outcome

- Kujala scores (reflecting functional outcome and pain) at three, six weeks and three, six and twelve months.

- SF-36 scores (reflecting quality of life) at three, six weeks and three, six and twelve months.

- The effect of a brace or plaster treatment on the level of pain experienced by the patients (VAS) at three, six weeks and three, six and twelve months.

- The range of motion (extension, flexion) of the knee joint at six weeks and three, six and twelve months. The range of motion will be measured by the research coordinator or research assistant with a goniometer.

- To examine the effect of a brace versus plaster treatment on reluxation rate at three, six weeks and three, six and twelve months.

- Complications as venous thrombosis and neurological deficit.

Study description

Background summary

Acute patellar dislocations are relatively common. The incidence of primary patellar dislocation is 5.8 per 100,000, and this increases to twenty-nine per 100,000 in the ten to seventeen-year-old age group.
Acute patellar dislocations may result in patellar instability, pain, recurrent dislocations, decreased level of sporting activity and patellofemoral arthritis. Occasionally, spontaneous reduction occurs, but if not, closed reduction can easily be performed at the emergency ward. Following reposition of the patella, different treatment modalities are described like plaster immobilisation, surgical treatment of ruptured ligaments or functional treatment.
According to recent literature, non-operative treatment is recommended for primary patellar dislocations. However, no well-designed studies assessing the most appropriate form and/or length of initial mobilization have been published.
In a systematic review by Stefancin it is stated that patients should be briefly immobilized (2-3 weeks).5 Colvin et al recommend non-operative treatment with patellar bracing.
In most hospitals in the Netherlands patients with acute patellar dislocation are treated with plaster/brace immobilization during 6 weeks.
However, following 6 weeks immobilization of the knee patients will have significant atrophy of the quadriceps muscles. The vastus medialis obliquus is the first part of the quadriceps to weaken and the last to strengthen when function is inhibited. It is recognized that atrophy of the vastus medialis is correlated with lateral instability. Therefore, our hypothesis is that prevention of vastus medialis atrophy is associated with a positive effect on knee function and re-luxation rate.

Study objective

Functional treatment with a brace and early physiotherapy will result in improved Kujala scores (reflecting better functional outcome with less pain) and SF-36 scores (reflecting higher quality of life) at 1 year compared with plaster immobilization following primary patella luxation.
Functional treatment with a brace results in a similar reluxation rate at 1 year compared with plaster treatment.

Study design

Randomized controlled multicentre trial: all patients =/> 12 years with a first-time traumatic patella luxation are included. In all patients the patella luxation will be reduced. Patients with a complex luxation (combined with a fracture) are excluded. The strategy involves plaster for one week in both

groups followed by a stabilizing brace for 2 weeks, combined with a well defined physiotherapy protocol for the first group and (regular) plaster treatment during 5 more weeks for the second group of patients. Clinical function, pain and reluxation rate will be monitored at regular intervals over the subsequent 12 months (1 week (pain), 3 weeks, 6 weeks, 3 months, 6 months and 12 months).

Intervention

The first group will be treated with plaster during 6 weeks.
The other group (intervention group) will be treated plaster during 1 week, followed by a stabilizing brace for 2 weeks and physiotherapie (After one week).

Study burden and risks

There are no risks associated with participation. Both treatment modalities are non-invasive. The only disadvantage for the participants is the time consumed by filling-in the questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Men or women aged 12 years and older (with no upper age limit)
2. A simple (without fracture) primary luxation of the patella
3. Provision of informed consent by patient and/or parents

Exclusion criteria

1. Patients =/< 11 years of age.
2. Patients with a complex (with fracture) luxation
3. Patients with pathological, recurrent or open luxations.
4. Patients with a complex knee function (i.e., stiff or painful knee, anatomic variation (valgus/varus) or neurological disorder of the lower limb) prior to the injury.
5. Retained hardware around the affected knee.
6. Patients with a disorder of bone metabolism other than osteoporosis (i.e., Paget*s disease, renal osteodystrophy, osteomalacia).
7. Patients with a connective tissue disease or (joint) hyper flexibility disorder, such as Marfan, Ehler Danlos and other related disorders
8. Likely problems, in the judgment of the investigators, with maintaining follow-up (e.g., patients with no fixed address will be excluded).
9. Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information in the judgment of the attending physician.
10. Patient with multiple injuries.
11. High Energetic Trauma patients
12. Comatose patients.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2009
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	brace
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-09-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL26998.098.09