Light traumacare in the general practice

Published: 08-05-2017
Last updated: 12-04-2024

To assess treatment results of light trauma care in the primary care setting, in comparison to light trauma care in the secondary care setting. In addition, we aim to study time consumption and costs.

Ethical review	Not approved
Status	Will not start
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON45519

Source
ToetsingOnline

Brief title
Light traumacare in the general practice

Condition

- Bone and joint therapeutic procedures

Synonym
fracture treatment, treatment of broken bones

Research involving
Human

Sponsors and support

Primary sponsor: Zorgverzekeraar De Friesland
Source(s) of monetary or material Support: De Friesland zorgverzekeraar

Intervention

Keyword: Fractures, General practice, Light traumacare, Primary care setting

Outcome measures

Primary outcome

- Patient satisfaction (questionnaires after 1, 6, and 12 weeks)

Secondary outcome

- General health (GHQ questionnaire), age, SES (after 1 week)

- Complications (e.g. secondary dislocation and pain scores; questionnaire

after 12 weeks)

- Physical function (questionnaire after 12 weeks)

- Time consumption (questionnaires after 1, 6, and 12 weeks)

- Costs (economic evaluation; questionnaire after 12 weeks).

Study description

Background summary

In the Netherlands, diagnostics and treatment of non-complex fractures or dislocations are generally organized in the secondary care setting. In contrast, since 2012 the general practice *Zorgplein Lemmer* uses X-ray diagnostics for selected groups of patients, including those with light traumas. The X-ray*s are digitally transmitted to the radiologist, saving the patient a visit to the hospital. However, when a fracture or dislocation is diagnosed, the patient still needs to be transported to the hospital to get treatment. Nowadays, substitution of care from the secondary to the primary care setting is stimulated by the government and insurers and in that light we aim to study the treatment results of light trauma care for non-complex fractures or dislocations in the primary care setting. When the general practitioners in our study obtain similar treatment results as the nearby hospitals, light trauma care may be substituted nationwide and beyond.

Study objective

To assess treatment results of light trauma care in the primary care setting, in comparison to light trauma care in the secondary care setting. In addition, we aim to study time consumption and costs.

Study design

Quasi-randomized non-inferiority trial (patients presenting on Monday, Wednesday, or Friday 08.00-11.30: intervention group; patients presenting on Monday, Wednesday, or Friday afternoon or Tuesday and Thursday: control group).

Intervention

Treatment in the general practice (intervention group) or in the hospital (control group), in both groups by qualified personnel and in accordance with equal national guidelines.

Study burden and risks

There is a very low risk associated with participating in this study, namely the treatment results in the primary care setting might be inferior compared to treatment in the emergency department. To reduce quality concerns, the participating general practitioners will be extensively trained and are encouraged to contact a radiologist, trauma surgeon or emergency care doctor at any moment. The burden for participating patients will very low because they will only be asked to fill in a few questionnaires, which take about one and a half hours in total to fill in.

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

200 patients (*12 years old) with non-complex fractures or dislocations which may be treated in the primary care setting.

Exclusion criteria

Complex fractures/dislocations which may not be safely treated in the general practice, or fractures/dislocations presented outside regular working hours.

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: Will not start

Enrollment:	200
Type:	Anticipated

Ethics review

Not approved

Date:	08-05-2017
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL59525.099.17