Amsterdam Wrist Rules in Children, a clinical decision aid.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26553

Source
NTR

Brief title
AWR in children

Health condition

wrist fracture, children, clinical decision aid,
pols fractuur, kinderen, klinische beslisregel

Sponsors and support

Primary sponsor: Academic Medical Centre
Source(s) of monetary or material Support: Academic Medical Centre

Intervention

Outcome measures

Primary outcome

1. The number of applied X-rays in children with acute injury of the wrist after implementation of the AWR;

2. The number of missed fractures of the distal radius/ulna fracture in children after

implementation of the AWR.

Secondary outcome

1. The number of X-rays that show a fracture of the distal radius fracture;

2. Reducing the time that patients with acute wrist injury spent at the ED;

3. Economic analysis.

Study description

Background summary

Rationale:

Acute trauma of the wrist is one of the most frequent motives for children visiting the Emergency Department (ED). Generally, these patients are routinely referred for radiological examination. Most X-rays however, do not reveal any fractures. A clinical decision rule concerning the X-ray referral policy may help to select and percolate patients with fractures.

Objective:

To formulate a clinical decision rule to predict the presence of a distal radius/ulna fracture in children after wrist trauma, presenting to the Emergency Department and to validate this rule in a new population.

Study design:

Cross sectional, observational diagnostic study.

Study population:

All consecutive children (age 3-16 year) presenting at the Emergency Department in the participating hospitals with acute wrist trauma.

Main study parameters/endpoints:

Outcome: Distal radius/ulna fracture.

Parameters: Multiple clinical variables which can be assessed on physical examination. These parameters will be described in detail in the methods section.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Any burden or risk for the participating patients additional to standard patient care in not applicable. Clinical examination and X-rays are performed as usual.

Study objective

Patients with a wrist trauma represent a substantial part of the patient population at the Emergency Department. Most hospitals routinely carry out a radiological examination of patients following wrist trauma to exclude a distal radius/ulna fracture. However, a large part of x-rays in these patients (50%) do not show a fracture. Consequently, this means a waste of resources, an increase in patient waiting time and unnecessary radiation exposure.
The applicants have developed a clinical decision rule to indicate the need for radiological examination for wrist injuries in children, called the Amsterdam Wrist Rules (AWR). The objective of this study is to evaluate the decrease in requested radiographs in case of a wrist injury with a suspicion of a distal radius fracture. In addition a cost-effectiveness analysis will be performed of direct and indirect medical costs.

Study design

1. Jan- march: Development of clinical decision aid;

2. April - august: Validation of clinical decision aid.

Primairy outcomes: Timpepoint 2 years;

Secondary outcomes: Timepoint 2 years.

Intervention

None.

Contacts

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Eligibility criteria

Inclusion criteria

Children aged beteen 3-16 years and a history of isloated wrist trauma within 72 h of presentation.

Exclusion criteria

1. Children younger than 3 years old;

2. Children older than 16 years old;

3. Children who went by radiography (elsewere) before our assesment;

4. Patients with pre-existing musculoskeletal disease, coagulopathy, or delvelopmental delay;

5. Patients with previous histroy of surgery or recent (<3 months) injury of the affected wrist;

6. Children with multisystem trauma;

7. Clinical suspicion of a scaphoid fracture.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2011
Enrollment:	1200
Type:	Actual

Ethics review

Positive opinion

Date:	12-12-2010
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	NL2533
NTR-old	NTR2651
Other	ABR : 34976.018.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A