

Amsterdam Wrist Rules in Children, a clinical decision aid.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26553

Bron

NTR

Verkorte titel

AWR in children

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Centre

Overige ondersteuning: Academic Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 is not applicable. Clinical examination and X-rays are performed as usual.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Jan- march: Development of clinical decision aid;
2. April - august: Validation of clinical decision aid.

Primary outcomes: Timepoint 2 years;

Secondary outcomes: Timepoint 2 years.

Onderzoeksproduct en/of interventie

None.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Children younger than 3 years old;
2. Children older than 16 years old;
3. Children who went by radiography (elsewhere) before our assesment;
4. Patients with pre-existing musculoskeletal disease, coagulopathy, or developmental delay;
5. Patients with previous history of surgery or recent (<3 months) injury of the affected wrist;
6. Children with multisystem trauma;
7. Clinical suspicion of a scaphoid fracture.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	1200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	12-12-2010
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	NL2533
NTR-old	NTR2651
Ander register	ABR : 34976.018.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A