Impact of clinical decision support on paediatric emergency care.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22275

Bron
Nationaal Trial Register

Aandoening

Children with vomiting/ diarrhea constitute about 15% of the pediatric emergency admissions1. Children under the age of five are most infected with viral pathogens as Rota and Noro. The clinical manifestations of viral gastroenteritis include diarrhea, vomiting, fever, anorexia, headache, abdominal cramps and myalgia. The constellation of symptoms varies from day to day and from person to person. Illness usually begins 12 hours to four days after exposure and generally lasts for three to seven days. Usually these diseases are self limiting, but these children are at risk for dehydration. In current practice, these patients are triaged by the nurse then evaluated by the physician for hydration status and diagnosis and, if necessary, fluid replacement therapy is started. Although oral rehydration therapy is the preferred treatment for mild to moderate dehydration, it remains underused. A consensus based guideline2 with assessment for hydration status and recommendations on oral rehydration by experienced emergency care nurses reduced in a before-after trial the number of intravenous rehydrations, unscheduled readmissions and total time spent in hospital3.

1 Bouwhuis et al. Ned Tijdschr Geneeskd. 2001;145:1847-51.
2 Armon et al. Arch Dis Child. 2001;85:132-42.
3 Boyd et al. Emerg Med J. 2005;22:116-7.

Ondersteuning

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Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient outcome:
1. Correct diagnosis (children with dehydration due to vomiting/diarrhea);
2. False positive errors (children without the target diagnosis incorrectly exposed to treatment);
3. False negative errors (children with the target diagnosis incorrectly refrained from treatment).

Toelichting onderzoek

Achtergrond van het onderzoek

OBJECTIVE

To assess the impact of a therapeutic decision rule for children with vomiting/ diarrhea, at risk for dehydration on patient outcome and costs.

STUDY DESIGN

We will perform a randomized controlled trial on the cost-effectiveness of a therapeutic decision rule for children with vomiting and diarrhea presenting at the emergency department. Randomization will be at individual patient level.

STUDY POPULATION

Children aged 1 month to 5 years visiting the emergency department of the ErasmusMC-Sophia Children's Hospital with acute vomiting/diarrhea. Children with chronic morbidity are excluded.

INTERVENTION

We will evaluate a therapeutic decision rule to start early rehydration treatment in children with vomiting/diarrhea who are at risk for dehydration.

OUCOME MEASURES

Patient outcome: Correct diagnosis of dehydration, false positive errors and false negative errors.

Process outcomes: Patient's consultation time, Number of return visits emergency department, Number of diagnostic tests and treatment, Hospitalisation. Costs of process outcomes.

POWER ANALYSIS

We expect to include 450 children with acute vomiting/diarrhea in 24 months. These numbers allow for reliable assessment of actual impact on patient outcome of the considered decision rule. The study allows to detect a 10-15% reduction in false positive errors with a power of 80% and type 1 error of 5%. It also allows to detect a difference of 10 minutes consultation time.

IMPACT ANALYSIS

Patient outcome of the decision rule is assessed by comparing the number of false positives and false negative errors in patients assigned to the decision rule with the patients assigned to usual care. The actual patient outcome is compared with the potential patient outcome based on the rule's recommendations regardless of implementation. Preserved validity of the original prediction rule is evaluated by comparing the rule's discriminative value in the new population to this value in the original population.

ECONOMIC EVALUATION

Cost-effectiveness is assessed by calculating the incremental cost-effectiveness ratio. Analysis will be performed from the hospital perspective. Effects are differences in the number of false positive and false negative errors, where false positive errors will be weighted as clinically less important than false negative errors. Costs will be estimated on resource use and unit costs.

TIME SCHEDULE

Dec 2009 - May 2010: integrating the decision rule with the electronic patient record and triage system introduction of the decision rule to the paediatric emergency nursing staff. Training of the paediatric emergency nursing staff to apply the decision rule.

May 2010 - July 2012: prospective randomized application of the decision rule with randomization at individual patient level.

August 2012 - Okt 2012: impact analysis and cost-effectiveness analysis, publication of the results.

Doel van het onderzoek

Evidence based medicine is the standard for current clinical practice. Guidelines and decision rules are developed to support medical decision making. Application of decision rules are supposed to improve efficiency and quality of care by early recommendations on diagnostic tests or treatment. In the process of translating prediction rules into practice impact analysis is required to show whether or not the decision rule actually improves clinical decisions and will benefit patient care or reduces costs.

Children with vomiting/ diarrhea constitute about 15% of the pediatric emergency admissions. These children are at risk for dehydration. Although oral rehydration therapy is the preferred treatment for mild to moderate dehydration, it remains underused. We now introduce a clinical decision support system (CDSS) focusing on this acute paediatric problem with challenging therapeutic dilemmas. We will evaluate a therapeutic decision rule to start early treatment in children with vomiting/diarrhea who are at risk for dehydration. Study results are expected to determine the optimal therapeutic strategy for children with vomiting/diarrhea at the emergency department (ED). We hypothesize an increase in the number of correct diagnosis (children with dehydration due to vomiting/diarrhea), a decrease of false positive errors (children without the target diagnosis incorrectly exposed to treatment) and a decrease of false negative errors (children with the target diagnosis incorrectly refrained from treatment). We hypothesize that this decision support system will be a more accurate predictor for the degree of dehydration and improves clinical care. Last we hypothesis that the patient's consultation time will be shorter, there will be less return visits to the emergency department, children will be less hospitalized and costs of these process outcomes will be reduced.

Onderzoeksopzet

Timepoint 0: All children are routinely evaluated by ED nurses during there visit to the emergency department. Patient characteristics, symptoms, observations and measures from physical examinations are registered by the nurse in a structured data entry application (SDE), as well as working diagnosis and final diagnosis and follow-up appointments.

Primary outcome: The correct presence of dehydration due to gastroenteritis is defined as an increase of weight or an improvement of vital signs including heart rate and capillary refill or urine production within 12-24 hours after treatment (oral or intravenous rehydration). In children not receiving rehydration therapy correct absence of dehydration is defined as non-complicated follow-up within a week. Children who are classified as being dehydrated and treated as such but who do not improve in weight or vital signs, are considered to be false positive errors. False negative errors refer to the children not undergoing rehydration therapy with complicated follow-up.

Secundary outcome: Patient's consultation time, the number of return visits to the emergency department, the number of diagnostic tests and treatment and hospitalisation are measured using the SDE application.

Costs are estimated on resource use and unit costs and include emergency care visit, health practitioner activities, diagnostic procedures, medical treatment, inpatient days in hospital and costs of adverse event of missed diagnosis (unscheduled readmissions, prolonged hospitalization, increased diagnostic test).

Onderzoeksproduct en/of interventie

1. Arm 1: Intervention arm (= 'therapeutic decision rule'), to start early treatment in children with vomiting/diarrhea who are at risk for dehydration. The 3 options of the ‘model’:

A. 0-4% dehydration: 30 ml/ kg Oral Rehydration Solution (ORS) per os in 1 hour;

B. 5-10% dehydration: 80 ml/ kg ORS per probe in 3 hours;

C. >10% dehydration: Consult physician;

2. Arm 2: 'Usual care' (controls).

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children aged 1 month - 5 years, visiting the pediatric emergency department of the ErasmusMC-Sophia with acute vomiting/diarrhea.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Chronic diarrhea (> 7 days);

2. Symptoms suggesting other focus (lower respiratory tract infections, urinary tract infections, joint problems etc.);

3. Children with pre-existing anatomical urogenital and/ or neurological abnormalities, renal/ pulmonary or cardiac disease;

4. Congenital or acquired immunodeficiency diseases and multiple disabled children.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2010
Aantal proefpersonen:	450
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	28-04-2010
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	NL2180
NTR-old	NTR2304
Ander register	ZonMW / METC-MEC : 17099.2503 / mec-2008-071 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A