Parental Instructions for Analgesic Use in the Emergency Department

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON28281

Source
NTR

Brief title
PAIN Study

Health condition

Pediatric, Instructions, Analgesics, Emergency Department

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Fonds Stichting Gezondheidszorg Spaarneland (SGS)

Intervention

Outcome measures

Primary outcome

Correct recall of provided information

Secondary outcome

Patient related: Pain score (Manchester pain scale) at day three. Parent satisfaction concerning the ED instructions.

Process related: Type, amount and dosing schedule of analgesics given by the parents. Number of days the pain medication was given. Number of revisits, contact with the ED

Safety related: percentage of overdosing

Influence of possible confounding factors on recall of information.

Compliance (post-implementation phase), was the written information, with link to the video provided at the ED.

Study description

Background summary

Rationale: Children with pain are often undertreated. Some parents are reluctant to give analgesics because they fear overdose, addiction and side effects. In general there seems to be a mismatch between provided information by the emergency department (ED) staff and the need for targeted information by parents. Many patients or their parents do not understand their instructions provided by the ED staff and furthermore are not aware of their lack in understanding and recall. We hypothesize that written, patient targeted and video discharge instructions at the ED will improve parents' knowledge about pain treatment, which will improve analgesic use.

Objective: The main objective is to evaluate the effect of written, patient targeted and video discharge instructions on parents' knowledge about pain treatment. The secondary aims are to study the effect of this implementation on patient, process and safety related outcomes. Possible confounders on recall and parent satisfaction will be assessed.

Study design: Multicenter study, conducted at the ED of the Erasmus MC and the Albert Schweitzer Hospital. The design of the study is a pre-implementation and post-implementation study; the implementation includes introduction of a written information leaflet for parents, with patient targeted instructions and an instruction video for parents. In the pre-implementation phase, usual care and in the post-implementation phase, the effect

of the written information and the instruction video will be evaluated. An independent researcher will contact the parents by phone within three to five days after the ED visit. An email address will be requested and, if provided, a link to an online questionnaire will be sent by e-mail. Filling out the questionnaire is regarded as providing informed consent.

Study population: Children aged 0-12 years presenting at the ED with pain and not requiring admittance to hospital. The treating physician gave the parents a prescription for analgesics or advised its use without providing a prescription.
Intervention: Parents will receive an instruction leaflet and a link to the online instruction video. The leaflet includes the preferred dosing and schedule of the advised analgesics. General information on pain and pain treatment will be provided in both the leaflet and the video

Main study parameters/endpoints: The intervention of written instructions should improve parents' knowledge (correct recall) with at least 15%, compared to the usual care group.

Study objective

We hypothesize that written, patient targeted and video discharge instructions at the ED will

Study design

To minimize the possible influences of seasonal differences, phase one is scheduled from February until June 2016 and phase two from August until December 2016.

Intervention

Parents from patients in the post-implementation phase (phase two of the study) will receive a written instruction leaflet with patient targeted information and a link to an instruction video.

Contacts

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Eligibility criteria

Inclusion criteria

• Age 0 - 12 years.

• Children with pain, for whom pain treatment after discharge from the ED to the home environment was advised / prescribed by the treating physician and noted in the patient file.

• Parents understand, speak and read Dutch.

Exclusion criteria

• No informed consent.

• Patients with pain who were admitted.

• Patients who were suspected of child abuse.

• Patients who took analgesics on a regular base (because of other co-morbidities, e.g. rheumatoid arthritis and sickle-cell disease).

Study design

Design

Intervention model: Other
Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2016
Enrollment:	326
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-05-2016
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	NL5737
NTR-old	NTR5882
Other	: MEC-2016-051

Study results