Pediatric Analgesia via the Intra-Nasal route. An observational multicenter prospective cohort study of atomized intranasal fentanyl in pediatric trauma patients in the emergency department

Published: 02-09-2015
Last updated: 21-04-2024

Primary objective:Our primary objective is to determine if the intranasal (IN) route is an effective, safe and quick alternative for intravenous fentanyl to treat acute pain in emergency department pediatric traumapatients. Secondary objectives:To...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON42266

Source
ToetsingOnline

Brief title
PAIN

Condition

- Bone and joint injuries

Synonym
dislocations, fractures, wounds or burns

Research involving
Human

Sponsors and support

Primary sponsor: Rode Kruis Ziekenhuis
Source(s) of monetary or material Support: geen

Intervention

Keyword: Emergency Department, Fentanyl, Intranasal, Pediatric

Outcome measures

Primary outcome

The primary outcome measure is painseverity measured by using an

age-appropriate validated pain score (VAS or WBFPS) at 10 min post-analgesia

and registration of adverse events, serious events and complications.

Secondary outcome

Secondairy outcome measures are

- pain severity at 0, 5, 20, 30, 60 minutes after analgesia administration

- time to administration

- doctor/nurse satisfaction scores

Study description

Background summary

Pain in traumapatients causes anxiousness and distress; it interferes with recovery and cure. Administrating adequate painrelief like intravenous fentanyl, can be challenging and painful for the patient. To avoid the intravenous route, fentanyl can also be administered via nasal spray.

Our hypothesis is that intranasal fentanyl will provide adequate painrelief and is safe in children with fractures, dislocations, wounds or burns in the emergency department.

Study objective

Primary objective:
Our primary objective is to determine if the intranasal (IN) route is an effective, safe and quick alternative for intravenous fentanyl to treat acute pain in emergency department pediatric traumapatients.

Secondary objectives:
To determine how fast the time to treatment is via the intranasal route
To determine the satisfaction scores of the nurse/doctor administering the intranasal fentanyl.

Study design

Multi-centre observational cohort study

Study burden and risks

Participation in the study brings nog additional risks for the patient.
Burdens associated with the study is a 60 minute stay in the Emergency department with monitoring and asking the painscore of the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Pediatric traumapatients >2yrs in the Emergency Department
Pain due to fractures, dislocations, wounds or burns
Receiving intranasal fentanyl

Exclusion criteria

Children younger than 2 yrs
No administration of intranasale fentanyl because of nasal obstruction, nose bleed or allergy for fentanyl
Legal guardian not able to sign informed consent

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	128
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	fentanyl
Generic name:	fentanyl
Product type:	Medicine
Brand name:	Instanyl
Generic name:	fentanyl

Ethics review

Approved WMO Date:	02-09-2015
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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
EudraCT	EUCTR2014-003214-85-NL
CCMO	NL49994.094.14