

Children*s attitude towards helmet use in traffic.

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Primary objective:The aim of this study is to investigate the number of children using a bicycle helmet after visiting the emergency department (ED) following a bicycle accident compared to children who have not.Secondary objective:The secondary...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON57450

Source

ToetsingOnline

Brief title

Child HELMED

Condition

- Other condition

Synonym

head injury, Maxillofacial injury

Health condition

aangezichtsfracturen

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: attitude, Children, helmet use, traffic

Outcome measures

Primary outcome

The main study parameter is helmet use.

Secondary outcome

The secondary parameter is attitude towards helmet use.

Study description

Background summary

Literature shows that helmet use is essential in the prevention of severe head injuries among children involved in bicycle accidents. However, helmet use in children remains low. Therefore, it is relevant to investigate the reason why helmet use among children is still low. In addition, it is unclear whether experiencing a serious bicycle accident influences helmet use and attitude towards helmet use among children.

Study objective

Primary objective:

The aim of this study is to investigate the number of children using a bicycle helmet after visiting the emergency department (ED) following a bicycle accident compared to children who have not.

Secondary objective:

The secondary objective is to investigate children's attitude towards helmet use after visiting the ED following a bicycle accident compared to children who have not.

Other objectives:

To investigate the association between period of time after visiting the ED and

attitude towards helmet use.

To investigate the association between type of injuries and attitude towards helmet use.

Study design

case control study

Study burden and risks

A short, questionnaire will be administered. It takes around 10 minutes. There are no invasive interventions and thereby the risk and burden associated with participation in this study is considered low. Participants younger than 12 years will be interviewed. This takes around 20 minutes.

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

To be eligible for participation in this study, a patient must meet all of the following criteria:

- Presentation at the ED of the Erasmus MC in Rotterdam between January 2017 and June 2024 after a bicycle accident.
- Informed consent is obtained
- Aged between 6 and 18 years at moment of inclusion
- A maximum score on the Glasgow Coma Scale at the time the questionnaire is administered.
- Time between accident and questionnaire is at least 3 months

Inclusion criteria for the control group:

- Informed consent is obtained
- Using a bicycle
- Aged between 6 and 18 years at moment of inclusion

Exclusion criteria

Patients who meet any of the following criteria will be excluded from participation in this study:

- A non-bicycle accident (e.g. pedestrian, scooter, car)
- Being a bicycle passenger
- Linguistic barrier (unable to answer questions in Dutch or English)

Exclusion criteria for the control group:

- Presentation to any emergency department after a bicycle accident in the past.
- Being a bicycle passenger
- Linguistic barrier (unable to answer questions in Dutch or English)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2025
Enrollment:	364
Type:	Anticipated

Ethics review

Approved WMO	
Date:	07-05-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL86991.078.24