

SPOKE trial

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24131

Source

Nationaal Trial Register

Health condition

spoke injuries, bicycle spoke injuries, wound,

Sponsors and support

Primary sponsor: Wintermans, S., Noordwest ziekenhuisgroep

Wilhelminalaan 12

1815 JD Alkmaar

s.wintermans@nwz.nl

072 - 548 4444

Source(s) of monetary or material Support: initiator

biodressings impregnated with polyhexamethylene are provided by Lohmann & Rausscher
(no conflict of interests)

Intervention

Outcome measures

Primary outcome

pain

Secondary outcome

wound infection

time to healing

Study description

Background summary

A common mechanism of injury in the Netherlands is when a child gets stuck with his or her foot between the spokes of a riding bicycle. The best wound treatment of these spoke-injuries is unclear, and especially with bandage renewal and evaluation of the wound, patients can have significant pain.

In this study we try to investigate whether treatment with a biodressing impregnated with polyhexamethylene biguanide gives less pain than the usual treatment which is a dressing with ointment.

The study design is a randomised controlled trial, in which the two treatments are compared: standard treatment with wound-dressing with ointment to prevent adhesion to the wound compared to biodressing impregnated with polyhexamethylene biguanide.

Study population will consist of children from 4-18 years with a spoke injury of the lower extremity.

Primary outcome is pain, as measured with a Faces Pain Scale-revised and a FLACC score. Secondary outcomes are duration of treatment and wound infection.

Study objective

wound treatment of foot and ankle injuries in children after a foot becomes caught in the spokes of a riding bicycle can be treated with less pain when using a biodressing

impregnated with polyhexamethylene instead of the usual ointment gauze bandage

Study design

first contact at emergency department, [day0]

appointments with treating MD and 'gipsverbandmeester'(cast master) untill wound has healed

Intervention

wound treatment with biodressing impregnated with polyhexamethylene

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

children 4-18 yrs

skin laceration/wound of foot and/or ankle after getting foot between spokes of a riding

bicycle

Exclusion criteria

<4yrs

>18yrs

allergic to any of the products used in the investigation

indication for surgery of underlying bone, muscle or tendon

intact skin

follow-up in other hospital

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	15-06-2016
Enrollment:	108
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 09-06-2016

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44741

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5475
NTR-old	NTR5892
CCMO	NL52326.094.15
OMON	NL-OMON44741

Study results