

SPOKE trial

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24131

Bron

Nationaal Trial Register

Aandoening

spoke injuries, bicycle spoke injuries, wound,

Ondersteuning

Primaire sponsor: Wintermans, S., Noordwest ziekenhuisgroep

Wilhelminalaan 12

1815 JD Alkmaar

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072 - 548 4444

Overige ondersteuning: initiator

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

first contact at emergency department, [day0]

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

Onderzoeksproduct en/of interventie

wound treatment with biodressing impregnated with polyhexamethylene

Contactpersonen

Publiek

Noordwest ziekenhuisgroep

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Wetenschappelijk

Noordwest ziekenhuisgroep

S. Wintermans
Wilhelminalaan 12

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The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

children 4-18 yrs

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

<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

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-06-2016
Aantal proefpersonen:	108
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 09-06-2016

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44741

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten