Evaluation of different wound dressings in the treatment of children with spoke injuries

Published: 26-04-2016
Last updated: 15-05-2024

To study wether a biodressing impregnated with polyhexamethylene biguanide in the treatment of spoke injuries in children could give a reduction in pain during the treatment compared to the standard treatment with wound dressing impregnated with

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Injuries NEC
Study type	Interventional

Summary

ID

NL-OMON44741

Source
ToetsingOnline

Brief title
SPOKE-trial

Condition

- Injuries NEC
- Skin and subcutaneous tissue disorders NEC

Synonym
injury after a foot between bicycle spokes, spokewound

Research involving
Human

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep
Source(s) of monetary or material Support: geen extra financiering;onderzoek wordt

verricht door AIOS tijdens opleidingsdagen en in vrije tijd

Intervention

Keyword: bandage, dressing, spoke injury, spokewound

Outcome measures

Primary outcome

Pain, as measured with Faces pain scale revised and a FLACC score

Secondary outcome

length of treatment in days

development of wound infection as scored with South-Hampton wound assessment

scale

Study description

Background summary

In the Netherlands most people ride a bicycle, but there are some risks entailed. Especially when children are riding along at the front or the back of the bicycle. It is possible for them to get there foot entamgled between the spokes of a riding bicycle, a so called spoke injury. Every year aproximately 2800 patients are presented on the emergency departments in the Netherlands. On the Emergency department in our hospital ecery year around 100 children are seen with spoke injuries. The treatment usually is a dressing with ointment or a silicone based wound dressing covered with a casted splint. At check up these wound dressings have to be removed to evaluate the wound. In the, often very young, patients this can be experienced as a painful procedure and check-ups can become a traumatising event.
Treatment with a biodressing impregnated with polyhexamethylene biguanide could offer some solution. This sort of dressing has been used in chronic and infected wounds. Treatment of spoke injuries in a small study in Amsterdam described good healing without infections. An important benefit coudl be a reduction in pain during treatment because the dressing doesn't have to be changed an you can see through it to check for any problems. The above mentioned study mentions a reduction in pain, there has however never been a study with a control group. Hypothesis is that this biodressing wth polyhexamethylene biguanide could reduce pain, and the use of this dressing in

the emergency department at the start of the treatment of the spoke injury coud be of benefit for the patients during the length of the treatment.

Study objective

To study wether a biodressing impregnated with polyhexamethylene biguanide in the treatment of spoke injuries in children could give a reduction in pain during the treatment compared to the standard treatment with wound dressing impregnated with

Study design

Randomised controlled trial, in wich 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.

Intervention

wound management with a biodressing impregnated with polyhexamethylene biguanide (SuprasorbX-PHMB)

Study burden and risks

Low burden, measurement of pain with pointing to a picture (Faces pain scale) for the patient and a short questionnaire (FLACC-score) for the parents/providers
The risk is low, there have been no allergic reactions described, previous study had no wound infections with the intervention treatment.

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

Children of 4 years of age and older.
Presentation within 72 hours after trauma
Wound on foot and/or ankle after inury where foot has been stuck in between spokes of riding bicycle.

Exclusion criteria

Children younger than 4 years,
Adults
unable to score pain on painscale
Allergic to a component of one of the bandages
Indication for surgery of underlying muscle, tendon or bone
No skin defect
Follow-up in another hospital

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-07-2016
Enrollment:	108
Type:	Actual

Medical products/devices used

Generic name:	biodressing impregnated with polyhexamethylene (Suprasorb X+PHMB)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-04-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24131
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL52326.094.15
OMON	NL-OMON24131