

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

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To study whether a biob dressing 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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Injuries NEC
<b>Study type</b>	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 their foot entangled between the spokes of a riding bicycle, a so called spoke injury. Every year approximately 2800 patients are presented on the emergency departments in the Netherlands. On the Emergency department in our hospital every 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 could be a reduction in pain during treatment because the dressing doesn't have to be changed and 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 with 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 could be of benefit for the patients during the length of the treatment.

### **Study objective**

To study whether a bi dressing 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 which the two treatments are compared: standard treatment with wound-dressing with ointment to prevent adhesion to the wound compared to bi dressing impregnated with polyhexamethylene biguanide.

### **Intervention**

wound management with a bi dressing 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**

### **Public**

Noordwest zieken

Wilhelminalaan 12  
Alkmaar 1815JD  
NL

### **Scientific**

Noordwest zieken

Wilhelminalaan 12  
Alkmaar 1815JD  
NL

## 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 injury where foot has been stuck in between spokes of riding bicycle.

### Exclusion criteria

Children younger than 4 years,

Adults

unable to score pain on pain scale

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: NTR

Title:

## In other registers

Register	ID
CCMO	NL52326.094.15
OMON	NL-OMON24131