

# Sterile versus clean suturing of traumatic wounds.

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The incidence and types of infection are comparable in sterile suturing or clean suturing of traumatic wounds. Clean suturing is cheaper, less time consuming and requires less assistance than sterile suturing

|                             |                          |
|-----------------------------|--------------------------|
| <b>Ethische beoordeling</b> | Positief advies          |
| <b>Status</b>               | Werving nog niet gestart |
| <b>Type aandoening</b>      | -                        |
| <b>Onderzoekstype</b>       | Interventie onderzoek    |

## Samenvatting

### ID

NL-OMON20060

### Bron

NTR

### Verkorte titel

SSH-study

### Aandoening

Sterile, Wound, Suturing, Emergency Department  
Steriel, Wond, Hechten, Spoedeisende Hulp

## Ondersteuning

**Primaire sponsor:** Erasmus Medical Centre Rotterdam  
The Netherlands

**Overige ondersteuning:** Fund is Initiator is Sponsor

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

The incidence of wound infections in steriel versus clean suturing procedure of traumatic wounds in a maximum follow up period of 14 days.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

The aim of this study is to find out if sterile and clean suturing of traumatic wounds in the Emergency Department are comparable looking at wound infection. Secondary we want to find out if clean suturing is cheaper, less time consuming and requires less assistance comparing with sterile suturing of traumatic wounds.

### **Doel van het onderzoek**

The incidence and types of infection are comparable in sterile suturing or clean suturing of traumatic wounds.

Clean suturing is cheaper, less time consuming and requires less assistance that sterile suturing

### **Onderzoeksopzet**

1. Woundinfection developping between suturing and suture removal (5-14 days);
2. Costs during intervention (day 1);
3. Need for assistance during intervention (day 1).

### **Onderzoeksproduct en/of interventie**

(Control) sterile suturing or (intervention) clean suturing.

Sterile suturing will be done with sterile gloves, sterile gauzes and sterile coveringcloth.

Clean suturing wil be done with clean boxed gloves, clean gauzes and without a covering cloth.

For both procedures, usage of extra materials and assistance will be documented.

All patients will return in after 5 to 14 days to the Emergency Department for suture removal

and wound assesment.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. ED presentation with traumatic suturing wound;
2. Age 18 years and older;
3. Informed consent.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Complicated wound: bitewound, vascular, tendon, nerve, ossale, cartilage injury;
2. Direct other intervention needed;
3. Treatment by doctor of orther speciality then emergengy medicine or surgery;

4. Signs of infection on ED presentation;

5. Wound older than 24 hours.

## Onderzoeksopzet

### Opzet

|                  |                       |
|------------------|-----------------------|
| Type:            | Interventie onderzoek |
| Onderzoeksmodel: | Parallel              |
| Toewijzing:      | Gerandomiseerd        |
| Blinding:        | Enkelblind            |
| Controle:        | Geneesmiddel          |

### Deelname

|                         |                          |
|-------------------------|--------------------------|
| Nederland               |                          |
| Status:                 | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-08-2012               |
| Aantal proefpersonen:   | 2140                     |
| Type:                   | Verwachte startdatum     |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 09-07-2012       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register       | ID                                                 |
|----------------|----------------------------------------------------|
| NTR-new        | NL3399                                             |
| NTR-old        | NTR3541                                            |
| Ander register | METC ErasmusMC / CCMO : 2011-306 / NL34798.078.11; |
| ISRCTN         | ISRCTN wordt niet meer aangevraagd.                |

## Resultaten

### Samenvatting resultaten

N/A