Sterile versus clean suturing of traumatic wounds

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Research if the incidence and types of wound infections are comparable in the sterile versus clean wound treatment.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON40023

Source
ToetsingOnline

Brief title
Traumatic wounds; sterile versus clean suturing

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
suturing, Wound treatment

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Emergency Department, sterile, suturing, wound

Outcome measures

Primary outcome

- the incidence of wound infections in steriel versus clean suturing procedure

of traumatic wounds in a maximum follow up period of 14 days

Secondary outcome

-Incidence of infection in subgroups

-Incidence of infection in different wound locations

-Incidence of infection in different wound types

-Incidence of infection in different time intervals between trauma and

presentation on the ED.

Study description

Background summary

In the Emergency Department (ED) traumatic wounds are very common. Of all the traumatic wouds seen in de ED 2,4%-7% become infected. Traumatic wounds, for example by falling in the street or a cut from a used knife, are in pricipal contaminated. This is in contradiction to the sterile surgical wounds in the operating theatre. Still today, despite the lack of evidence, the sterile technique is used and recommended for the treatment of traumatic wounds in the ED. Also in the Erasmus Medical Centre, Rotterdam and Sint Franciscus Gasthuis, Rotterdam the sterile technique is used. For suturing of traumatic wounds sterile gloves, gauzes, cloths and suturing materials are used.
In contrast to this Dutch General Practicioners suture using a partially or completely nonsterile technique and there are several hospitals in the Netherlands (e.g. Haga Hospital and Atrium Hospital) that, based on research, no longer use the sterile technique.
Strict sterile suturing is costly, frequently requires extra assistance and is more time consuming compaired to clean suturing. Also the sterile field is hard to maintain because of patient movements, reaching for materials by the docto and other situations in the ED where the docter needs to postpone the suturing and the sterile materials are left opened for al long period of time.
Presently in the literature there is only one study (Perelman et al. Ann Emerg Med. 2004;43:362-370) which compares sterile versus clean suturing. This study

showed no significant difference in the incidence of wound infections between wounds sutured under sterile or clean conditions.

Study objective

Research if the incidence and types of wound infections are comparable in the sterile versus clean wound treatment.

Study design

Prospective Randomised Multicentre Controlled Trail
Based on an expected prevalence of infection of 2.4%-7% in combination with an average of 70 wounds per month that need suturing, patients need to be recruited for 2.5 years to reach a statistical power of 80%. All patients above 18 years of age who present with a uncomplicated traumatic wound and are treated in the ED(by AIOS SEH/ANIOS SEH/NP'er/AIOS CHI/ANIOS CHI) will be included in the study. All patients with complicated wounds, patients who are not treated by an ED doctor or a surgeon or patients that can not give informed constent will be excluded.
The attending doctor will, in the privacy of patients room, discuss the study and information leaflet. After 30 minutes of thinking time the patient will be asked to give informed consent to take part in the study. Following the informed consent electronic randomisation will occur. Preparation of the wound and setting out the suturing materials will then be carried out by the nurse. Suturing (and when needed debridement) of the wound will then be done by the doctor. Preparation, cleaning, aneasthesia, debridement and suturing and the order of these actions are standardised in the sterile and clean protocol. The protocols differ in sterile or clean gloves and gauzes and the use of sterile cloths. After suturing the nurse will put a dressing on the wound and make an appointment for wound follow up. This appointment will coincide with suture removal. For this the guideline *wondbehandeling in de Eerste Hulp-afdeling* on the Kwaliteitsinformatie systeem (KIS) of the Erasmus Medical Centre will be used. Patients are instructed to return to the Emergency department if they see signs of infection. Patients will receive a wound brochure to explain this fully. The study forms will be completed by the attending docter. When besides the standard materialparcel extra material is used this will be filled in on the material form by the docter. During the follow up appointment the wound will be examined by a staff Emergency Physician or a Surgeon and the wound control form will be completed. If the patient notes that there were signs of infection of the wound earlier, but during removal of the sutures no signs of infection are seen, this will be considered irrelevant. If patient not attend the follow up appointment, they will be contacted by telephone.

Intervention

Sterile versus clean suturing

Study burden and risks

No extra risks then the risks of suturing a traumatic wound

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- ED presentation with traumatic suturing wound
- Age 18 years and older
- Informed consent

Exclusion criteria

-complicated wound: bitewound, vascular, tendon and/or nerve injury, fracture/cartilage injury
-OR intervention needed
-treatment by doctor of orther speciality then emergengy medicine or surgery
-signs of infection on ED presentation
-wound older then 24 hours

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-07-2012
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO

Date:	03-02-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	20-12-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL34798.078.11