

Sterile versus clean suturing of traumatic wounds.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20060

Source

NTR

Brief title

SSH-study

Health condition

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

Sponsors and support

Primary sponsor: Erasmus Medical Centre Rotterdam

The Netherlands

Source(s) of monetary or material Support: Fund is Initiator is Sponsor

Intervention

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

1. Are there any factors influencing the development of wound infection in both groups?
2. Is there a difference in costs and the need for assistance between both groups?

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

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

Clean suturing will 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.

Contacts

Public

's Gravendijkwal 230
J.J.M. Zwaans
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7040704

Scientific

's Gravendijkwal 230
J.J.M. Zwaans
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7040704

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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 then 24 hours.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2012
Enrollment:	2140
Type:	Anticipated

Ethics review

Positive opinion	
Date:	09-07-2012
Application type:	First submission

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
NTR-new	NL3399
NTR-old	NTR3541
Other	METC ErasmusMC / CCMO : 2011-306 / NL34798.078.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A