A study into a new test for the rapid diagnosis of a wound infection in wounds with prolonged existance: The InFact 2.0 study.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26712

Source
Nationaal Trial Register

Brief title
INFACT 2

Health condition

Chronic wounds (> 3 weeks)

Sponsors and support

Primary sponsor: University of Graz, Austria
Source(s) of monetary or material Support: University of Graz, Austria

Intervention

Outcome measures

Primary outcome

Sensitivity, specificity, positive and negative predictive value and the AUC of the enzyme

analyses with wound biopsies as gold standard are the main study parameters.

Secondary outcome

To determine the clinical relevance of the enzyme analyses, the diagnostic properties of both wound swab and clinical judgment, when compared to wound biopsies, will be calculated.

Furthermore, the enzyme analyses should point out what enzymes are present in the wound fluid.
The types of bacteria that causes the infection is identified from wound biopsy.

Study description

Background summary

Rationale:

The current diagnostic methods to identify infection in chronic wounds are based on clinical judgment and, when wound infection is suspected, a wound swab for microbiological analysis. The gold standard, wound biopsy, is only used in rare cases. However, these current diagnostic methods seem unreliable (clinical judgment) or provide results only after a couple of days (cultures). Late diagnosis of wound infection can result in hospitalization and, in worst cases, sepsis. A new diagnostic tool, the InFact, is based on the identification of the enzymes myeloperoxidase, human neutrophil elastase and lysozyme that are proven to play a role in the inflammation process. Using these enzyme analyses has the potential to detect wound infection both fast and accurate.

Objective:

The primary objective of the study is to determine sensitivity, specificity, positive and negative predictive value of the enzyme analyses (myeloperoxidase, human neutrophil elastase and lysozyme) with wound biopsies as the gold standard. Furthermore, microbiological analysis based on wound swabs and the clinical judgment will be compared with the biopsy results.

Study design:

This diagnostic study is designed as a cross-sectional study.

Study population:

The study population consist of adult patients (≥ 18 years) with chronic wounds, presenting at the departments of dermatology and vascular surgery of the Medisch Spectrum Twente Hospital, Enschede.

Main study parameters/endpoints:

Sensitivity, specificity, positive and negative
predictive value and the AUC of the enzyme analyses with wound biopsies as gold standard are the main study parameters.

Study objective

The current diagnostic methods to identify infection in chronic wounds are based on clinical judgment and, when wound infection is suspected, a wound swab for microbiological analysis. The gold standard, wound biopsy, is only used in rare cases. However, these current diagnostic methods seem unreliable (clinical judgment) or provide results only after a couple of days (cultures). Late diagnosis of wound infection can result in hospitalization and, in worst cases, sepsis. A new diagnostic tool, the InFact, is based on the identification of the enzymes myeloperoxidase, human neutrophil elastase and lysozyme that are proven to play a role in the inflammation process. Using these enzyme analyses has the potential to detect wound infection both fast and accurate. The primary objective of the study is to determine sensitivity, specificity, positive and negative predictive value of the enzyme analyses, with wound biopsies as the gold standard.

Study design

To determine the diagnostic properties of the enzym analyses; both a wound swab for enzymanalyses and a biopsy for microbiological analyses will be taken as a one-time assessment during the patient's regular appointment at the hospital.

To determine the clinical relevance of the enzyme analyses, the wound will be assessed through clinical judgment and a wound swab for microbiological analysis.

These four diagnostic tests will be performed during the regular appointment in the following order:

1. Clinical judgment of the wound;

2. Wound swab for enzyme analyses;

3. Wound swab for microbiological analysis;

4. Biopsy.

Intervention

There are no interventions because this is a diagnostic study.

Contacts

Public
Medisch Spectrum Twente,
P.O. Box 50000

J. Palen, van der
Enschede 7500 KA
The Netherlands
+31 (0)53 4872023
Scientific
Medisch Spectrum Twente,
P.O. Box 50000

J. Palen, van der
Enschede 7500 KA
The Netherlands
+31 (0)53 4872023

Eligibility criteria

Inclusion criteria

1. Open chronic wound (>3 weeks); this will be mainly:

A. Diabetic foot ulcer;

B. Ulcus cruris (arterial or venous);

C. Decubitus ulcer;

D. Operation wounds, healed by secundary intention or wound dehiscention.

2. ≥ 18 years of age;

3. Patients from the department of Surgery or Dermatology.

Exclusion criteria

1. Use of antibiotics in the last five days;

2. Malignant wounds;

3. Fully necrotic wounds;

4. Fully dry wounds; no production of wound fluid in last 2 days;

5. Allergy or hypersensitivity for Lidocaine, when local anaesthesia is necessary;

6. Wounds that are completely covered with exposed periosteum;

7. Wounds with a diameter < 2 millimeters;

8. Facial wounds;

9. Haematological disorders with risk of uncontrolled bleeding.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-04-2013
Enrollment:	200
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 40347
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3706
NTR-old	NTR3904
CCMO	NL43733.044.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40347

Study results

Summary results
N/A