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

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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....

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26712

Bron
Nationaal Trial Register

Verkorte titel
INFACT 2

Aandoening

Chronic wounds (> 3 weeks)

Ondersteuning

Primaire sponsor: University of Graz, Austria
Overige ondersteuning: University of Graz, Austria

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

There are no interventions because this is a diagnostic study.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2013
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40347
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A