A Study Into The Diagnostic Properties Of A New Device For Rapid Bedside Testing Of Infection In Chronic Wounds: The INFACT 2.0 study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON40347

Source
ToetsingOnline

Brief title
INFACT 2

Condition

- Bacterial infectious disorders

Synonym
wound infection, wound inflammation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Universiteit van Graz;Oostenrijk

Intervention

Keyword: Chronic wounds, Diagnostics, Enzyme analyses, Wound infection

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

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.

Study 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 burden and risks

For patients, participation in this study consists of a onetime assessment during a regular appointment. Clinical judgment and wound swabs for microbiological analysis are part of regular care. Only when wound infection is not expected based on clinical judgment, wound swab for microbiological analyses can be seen as additional test. No risks are associated with the clinical judgment, the wound swab for microbiological analysis and the additional wound swab enzyme analysis.
The wound biopsy that is taken for this study might cause local bleeding. In this study, patients at risk of uncontrolled bleeding are excluded. In case there is bleeding of the wound, adequate haematosis will be achieved through covering the wound with calcium alginate gauze and, if necessary, with a pressure dressing. Furthermore, patients might experience some pain during the wound biopsy. To minimize this pain, the wound will be anesthetized before biopsy with Lidocaine drops if necessary.

Contacts

Public
Medisch Spectrum Twente

Haaksbergerstraat 55
Enschede 7513 ER
NL
Scientific
Medisch Spectrum Twente

Haaksbergerstraat 55

Enschede 7513 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Open chronic wound (>3 weeks); this will be mainly
o Diabetic foot ulcer
o Arterial or venous leg ulcer
o Pressure ulcer
o Operation wounds, healed by secundary intention or wound dehiscention.
>=18 years of age
Patients from the department of Surgery (MST, ZGT, St Jansdal, SKB) or Dermatology (MST), or from Livio home care

Exclusion criteria

• Use of antibiotics in the last five days
• Malignant wounds
• Fully necrotic wounds
• Fully dry wounds; no production of wound fluid in last 2 days.
• Allergy or hypersensitivity for Lidocaine, when local anaesthesia is necessary. This will be based on self-reported allergy or hypersensitivity by the patient.
• Wounds that are completely covered with exposed periosteum
• Wounds with a diameter < 3 millimetres
• Facial wounds
• Haematological disorders with risk of uncontrolled bleeding
• INR > 4
• MRSA or ESBL positive

• Additional exclusion criteria for Livio home care; wounds that are not located on extremities

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-05-2013
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	02-04-2013
Application type:	First submission
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	16-04-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	19-11-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	27-05-2014
Application type:	Amendment

Review commission:	METC Twente (Enschede)
Approved WMO Date:	20-01-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26712
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL43733.044.13
OMON	NL-OMON26712

Study results

Date completed:	31-12-2015
Actual enrolment:	180