

# Randomised controlled trial of the use of three dressing regimens in the management of chronic ulcers of the foot in diabetes.

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 14/03/2014	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

N0116140783

# Study information

## Scientific Title

### Study objectives

1. The primary objective is to test whether modern dressings are more clinical effective than traditional dressings in the treatment of diabetes related foot ulcers. The dressings to be compared will be: a simple, traditional non-adherent preparation (N-A), a widely used modern antiseptic preparation (Inadine), and a new hydrofibre preparation of higher unit cost (Aquacel). All three dressings are widely used in clinical practices in the UK.
2. To investigate changes in ulcer size, condition and reoccurrence during the study period associated with each dressing.
3. To determine the cost-effectiveness associated with each of the three dressings.
4. To assess the patients' mood, satisfaction and quality of life associated with each of the three dressings.
5. To investigate the patient and carer contribution to care in terms of involvement with self-care, and to gain qualitative insights into the patient experience with each of the dressing interventions.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied

Nutritional, Metabolic, Endocrine: Diabetic foot

### Interventions

The dressings to be compared will be: a simple, traditional non-adherent preparation (N-A), a widely used modern antiseptic preparation (Inadine) and a new hydrofibre preparation of higher unit cost (Aquacel).

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/10/2003

**Completion date**

31/12/2006

**Eligibility****Key inclusion criteria**

Not provided at time of registration

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/10/2003

**Date of final enrolment**

31/12/2006

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Diabetic Foot Clinic**

London

United Kingdom

SE5 9RS

## **Sponsor information**

**Organisation**

Department of Health

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Kings College Hospital NHS Trust R&D Consortium (UK)

**Funder Name**

NHS R&D support funding

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration