

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

Submission date
30/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
30/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
14/03/2014

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ 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

Protocol serial number

N0116140783

Study information

Scientific Title

Study objectives

1. The primary objective is to test whether modern dressings are more clinically 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

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2006

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Diabetic Foot Clinic

London

United Kingdom

SE5 9RS

Sponsor information

Organisation

Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration