ISRCTN52817488 https://doi.org/10.1186/ISRCTN52817488

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

Registration date
30/09/2005

Overall study status
Completed

Last Edited
14/03/2014

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
Richmond House
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SW1A 2NL
+44 (0)20 7307 2622
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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