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PROtease modulating dressings in the treatment of chronic wounds: finding bioMARKers to predict healing response

Submission date	Recruitment status	[X] Prospectively registered
13/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/08/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/06/2017	Skin and Connective Tissue Diseases	[_] 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
N/A

Study information

Scientific Title
PROtease modulating dressings in the treatment of chronic wounds: finding bioMARKers to predict healing response

Acronym
ProMark

Study objectives
A chronic leg ulcer is defined as a wound between the knee and ankle joint that has not healed within four weeks. The aim of this study is to identify biomarkers which differentiate between leg ulcer patients whose wounds will and will not respond to treatment with protease modulating dressings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Original protocol: Leeds (West) Research Ethics Committee, 07/09/2006, ref: 06/Q1205/155
Version 2.0: 19/10/2006
Version 3.0: 17/05/2007

Study design
Prospective multi-centre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic leg ulcer

Interventions
Patients will be randomised to receive 12 weeks therapy with either:
1. PROMOGRAN™ Wound Modulating Matrix
2. PROMOGRAN PRISMA™ Wound Balancing Matrix

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Response to treatment defined as either a more than or equal to 50% wound area reduction from the baseline to the 12 week wound area measurements or complete healing by 12 weeks

Secondary outcome measures
1. Initial response to treatment at 6 weeks defined a more than or equal to 50% wound area reduction from the baseline to the 6 week wound area measurements or complete healing by 6 weeks
2. Percentage baseline wound area reduction by 12 weeks
3. Safety - serious adverse events

Overall study start date
01/03/2007

Completion date
30/12/2008

Eligibility

Key inclusion criteria
1. Aged 18 or over with a venous leg ulcer
2. Duration of ulcer greater than or equal to 30 days
3. Ulcer greater than or equal to 1 cm^2 in area
4. Ankle Brachial Pressure Index (ABPI) greater than or equal to 0.80
5. Written informed consent
6. Able to comply with study treatment and follow-up schedule

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria

Current exclusion criteria as of 07/07/2008:
1. Participating in another wound related study or intervention trial
2. Clinical signs of an infection of the target ulcer
3. Sharp debridement within past seven days
4. Pre-study (one month) treatment with therapies which affect wound healing including immunosuppressive therapy, dialysis, systemic corticosteroids, radiation therapy, chemotherapy, vascular or plastic surgery to the affected limb
5. Expected to require treatment with therapies which affect wound healing including immunosuppressive therapy, dialysis, systemic corticosteroids, radiation therapy or chemotherapy during the study period
6. Planned or expected to require vascular or plastic surgery to the affected limb, during the study period
7. Pre-study use (at any time) of the study dressings (PROMOGRAN™ Matrix and/or PROMOGRAN™ PRISMA Matrix)
8. Pre-study (one month) use of Active Wound Care Therapies
9. Pre-study (one week) use of silver-based products, larval therapy, iodine/povidone-iodine products, enzymatic debriding agents, topical corticosteroids, topical antibiotics, topical antifungal treatments, or antimicrobial agents (cleansing agents/dressings/topical treatments)
10. Known hypersensitivity to any of the dressing components
11. Life expectancy less than six months

Previous exclusion criteria:
1. Participating in another wound related study or intervention trial
2. Diabetes
3. Clinical signs of an infection of the target ulcer
4. Sharp debridement within past seven days
5. Pre-study (one month) treatment with therapies which affect wound healing including immunosuppressive therapy, dialysis, systemic corticosteroids, radiation therapy, chemotherapy, vascular or plastic surgery to the affected limb
6. Expected to require treatment with therapies which affect wound healing including immunosuppressive therapy, dialysis, systemic corticosteroids, radiation therapy or chemotherapy during the study period
7. Planned or expected to require vascular or plastic surgery to the affected limb, during the study period
8. Pre-study use (at any time) of the study dressings (PROMOGRAN™ Matrix and/or PROMOGRAN™ PRISMA Matrix)
9. Pre-study (one month) use of Active Wound Care Therapies
10. Pre-study (one week) use of silver-based products, larval therapy, iodine/povidone-iodine products, enzymatic debriding agents, topical corticosteroids, topical antibiotics, topical antifungal treatments, or antimicrobial agents (cleansing agents/dressings/topical treatments)
11. Known hypersensitivity to any of the dressing components
12. Life expectancy less than six months

Date of first enrolment
01/03/2007

Date of final enrolment
30/12/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
Leeds
United Kingdom
LS2 9NG

Sponsor information

Organisation
Johnson & Johnson Wound Management (UK)

Sponsor details
Johnson and Johnson Medical Ltd
Airebank Mills
Gargrave, Skipton
North Yorkshire
United Kingdom
BD23 3RX

Sponsor type
Industry

Website
http://www.jnjgateway.com/home.jhtml?loc=GBENG&page=viewContent&contentId=09008b98804404e4

ROR
https://ror.org/03qwpn290

Funder(s)

Funder type
Industry

Funder Name
Yorkshire Forward (UK)

Funder Name
Johnson & Johnson Wound Management (UK)

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