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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Screening

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Johnson & Johnson Wound Management (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes