

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 11/08/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/06/2017	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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Additional identifiers

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 cm² 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/03qwpm290>

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