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A preliminary single-centre, randomised, comparative study of the Eakin wound dressing in the management of superficial/partial thickness wounds

Submission date
11/05/2005

Registration date
15/06/2005

Last Edited
07/03/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Skin and Connective Tissue Diseases

[X] 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

Protocol serial number
TGE - W01

Study information

Scientific Title

A preliminary single-centre, randomised, comparative study of the Eakin wound dressing in the management of superficial/partial thickness wounds

Study objectives
Eakin wound dressing is effective and safe for use on humans with superficial/partial thickness wounds.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Wounds

Interventions
Eakin wound dressing will be trialled against a leading hydrocolloid wound dressing for a period of 5 weeks or until the wound has healed. Dressings will be changed every 4 days.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Eakin wound dressing

Primary outcome(s)
Confirmation of the clinical efficacy and safety of Eakin wound dressing when used in the treatment of superficial/partial thickness wounds. Wound is healed (or reduced in size) over a period of 5 weeks.

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/01/2006

Eligibility

Key inclusion criteria
All patients presenting superficial/partial thickness wounds which could or would normally be treated with a 'hydrocolloid' wound dressing, and who are not precluded by the exclusion criteria below, will be invited to participate in this clinical trial.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients will be excluded from the trial under the following circumstances:
1. Wound is >5 cm length or breadth
2. Wound is >0.5 cm depth
3. Wound involving muscle, tendon or bone
4. Wound infection is suspected
5. Where informed consent is withheld
6. Where patients are unable to give informed consent due to legal incompetence, unless informed consent is available from a responsible relative or guardian
7. Where, in the physician's opinion, inclusion in the trial is not advised

Date of first enrolment
01/10/2005

Date of final enrolment
31/01/2006

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Royal Group of Hospitals Trust
Belfast
United Kingdom
BT12 6BA

Sponsor information

Organisation
TG Eakin Limited (UK)

Funder(s)

Funder type
Industry

Funder Name
Full cost of trial will be funded by TG Eakin Limited (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration