

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	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 15/06/2005	Overall study status Completed	☐ Protocol
Last Edited 07/03/2017	Condition category Skin and Connective Tissue Diseases	☐ 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

Contact name

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Contact details

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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

Primary study design

Interventional

Study design

Single-centre randomised controlled trial

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