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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	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/06/2005	**Overall study status** Completed	
Last Edited 07/03/2017	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2005

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

Age group
Adult

Sex
Both

Target number of participants
40 hospital patients

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
Northern Ireland

United Kingdom

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

Sponsor information

Organisation
TG Eakin Limited (UK)

Sponsor details
15 Ballystockart Road
Comber
United Kingdom
BT23 5QY

Sponsor type
Industry

Website
http://www.eakin.co.uk/home.asp

Funder(s)

Funder type
Industry

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