

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

<b>Submission date</b> 11/05/2005	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/06/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/03/2017	<b>Condition category</b> 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

### Contact name

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### Contact details

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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