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A single-centre study of the clinical efficacy of Eakin cohesive paste

Submission date	Recruitment status	[X] Prospectively registered
24/01/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/03/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/02/2014	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.eakin.co.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TGE/P01

Study information

Scientific Title

Study objectives
Eakin cohesive paste is safe for use on patients with high output wounds and stomas.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Favourable ethical opinion received 16th September 2005.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Stoma, ostomy, wound and fistula

Interventions
The trial is a randomised cross over trial. Patients will be assigned a patient identity number and will then be randomly
assigned either to begin with their normal pouching regime or their normal pouching regime and Eakin cohesive paste. At the half way point the treatment will be
switched.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Confirmation of the safety and efficacy of Eakin cohesive paste

Secondary outcome measures
Determination of whether Eakin cohesive paste increases the pouch weartime on high output wounds.

Overall study start date
01/06/2005

Completion date
01/10/2005

Eligibility

Key inclusion criteria
Patients presenting wounds, stomas and fistulae with greater than 200 ml exudate per day.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
Patients will be excluded from the study under the following circumstances:
1. Where informed consent is withheld
2. Where the patient is unable to give informed consent due to legal incompetence
3. Where, in the physician's opinion, inclusion in the trial is not advised
4. Where the patient is presenting a critical wound, or is in an emergency situation
5. Where the patient is in the intensive care unit
6. Where there is an open wound in the peristomal region (for stoma patients only)
7. Where the patient is currently participating in another clinical trial
8. Where the patient has a known sensitivity to the product or any of its ingredients
8. Where the patient currently uses stoma paste as part of their regular pouching regime

Date of first enrolment
01/06/2005

Date of final enrolment
01/10/2005

Locations

Countries of recruitment
Northern Ireland

United Kingdom

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

Sponsor information

Organisation
T G Eakin Limited (UK)

Sponsor details
15 Ballystockart Road
Comber
United Kingdom
BT23 5QY

Sponsor type
Not defined

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

Funder(s)

Funder type
Industry

Funder Name
T G Eakin Limited

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