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A randomised prospective study to compare the use of skin staples versus Dermabond tissue adhesive in the management of wound healing in patients undergoing thyroid and parathyroid surgery: a pilot study

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 12/11/2008	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr P Moore

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0084144554

Study information

Scientific Title

Study objectives
Which method, the use of skin staples or Dermabond is most clinically and cost effective and acceptable to patients undergoing thyroid and parathyroid surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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
Surgery: Thyroid and parathyroid

Interventions
This study looks at the performance of skin adhesive Dermabond against the standard method of skin closure I.e. skin staples in elective thyroid or parathyroid surgery. If the result of the pilot study show the skin adhesive to be comparable or possibly superior to the staples then it will provide information for the design of a larger study, which will allow thorough statistical analysis of the performance of each method of skin closure.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Patients undergoing elective thyroid or parathyroid surgery under the care of Mr Moore will be invited to take part in the study until a cohort of 30 patients has been recruited.

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/11/2002

Completion date
30/11/2004

Eligibility

Key inclusion criteria
Patients who are over the age of 18 years and undergoing thyroid or parathyroid surgery, have no known allergy to the products used in this study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
30

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/11/2002

Date of final enrolment
30/11/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern Lincolnshire & Goole Hospitals NHS Trust
Scunthorpe
United Kingdom
DN15 7BH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Northern Lincolnshire and Goole Hospitals NHS Trust (UK), NHS R&D Support Funding

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2007		Yes	No