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A randomised prospective comparison of tissue adhesive (Dermabond) versus standard wound closure in elective paediatric orthopaedic surgery

Submission date
30/09/2005

Registration date
30/09/2005

Last Edited
07/04/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0188149758

Study information

Scientific Title

Study objectives
To compare tissue adhesive (Dermabond) to subcuticular suture for the skin closure in paediatric elective orthopaedic study.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Wound closure in orthopaedic surgery

Interventions
A prospective randomised controlled pilot study. Patients will be randomised to:
1. Tissue adhesive (Dermabond)
2. Standard wound closure

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure

1. Time for closure of wound
2. Early and late complications
3. Patients and physician's assessment of cosmetic appearance of the healed wound
4. Cost effectiveness

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2004

Completion date
01/08/2006

Eligibility

Key inclusion criteria
1. Patients who are more than 1 year old and less than 16
2. Undergoing elective orthopaedic procedures
3. In good health and without significant abnormalities
4. Agreeing to return for follow-up at 10 days, 6 weeks and 6 months

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Known bleeding diathesis
2. Insulin dependent diabetes mellitus
3. Known personal or family history of keloid formation or scar hypertrophy
4. Known allergy to cyanoacrylate compounds or formaldehyde

Date of first enrolment
01/01/2004

Date of final enrolment
01/08/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Orthopaedics Directorate
Chorley
United Kingdom
PR7 1PP

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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United Kingdom
SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name

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