

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

| | | |
|--|---|--|
| Submission date 30/09/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 30/09/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 07/04/2014 | Condition category Surgery | <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
Dr P Patil

Contact details
Orthopaedics Directorate
Chorley
United Kingdom
PR7 1PP

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 Years

Upper age limit

16 Years

Sex

All

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**

United Kingdom

England

Study participating centre

Orthopaedics Directorate

Chorley

United Kingdom

PR7 1PP

Sponsor information

Organisation

Department of Health

Funder(s)**Funder type**

Government

Funder Name

Lancashire Teaching Hospitals NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration