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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
30/09/2005	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	Results
Last Edited	Condition category	[] Individual participant data
07/04/2014	Surgery	<ul><li>Record updated in last year</li></ul>

# 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

**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 London United Kingdom SW1A 2NL +44 (0)20 7307 2622 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