

# Randomised controlled trial to evaluate two alternative strategies for the management of unerupted incisors obstructed by supernumerary teeth

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/01/2010	<b>Condition category</b> Oral Health	<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 Philip Benson

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N0059094047

# Study information

## Scientific Title

### Study objectives

1. To record the success rate and time to emergence of the unerupted incisor following initial surgery between groups
2. To determine any differences in the re-operation rate between the two groups
3. To determine differences (if any) in the periodontal status of the (originally) unerupted incisor in the two groups
4. To determine the average number of treatment visits required for each group
5. To determine the relative acceptability (from patient and parent perspectives) of each treatment method

### 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

Oral Health: Orthodontics

### Interventions

Not provided at time of registration

Notified 2005: trial stopped due to poor recruitment.

### Intervention Type

Other

**Phase**

Not Applicable

**Primary outcome measure**

Tooth eruption.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/2001

**Completion date**

01/01/2005

**Reason abandoned (if study stopped)**

Participant recruitment issue

## **Eligibility**

**Key inclusion criteria**

Children.

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/2001

**Date of final enrolment**

01/01/2005

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**University of Sheffield**  
Sheffield  
United Kingdom  
S10 2SZ

## **Sponsor information**

**Organisation**  
Department of Health (UK)

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Sheffield Teaching Hospitals (Central Campus) (UK)

## **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