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

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|---|---|---|
| **Submission date**<br>12/09/2003 | **Recruitment status**<br>Stopped | [ ] Prospectively registered<br>[ ] Protocol |
| **Registration date**<br>12/09/2003 | **Overall study status**<br>Stopped | [ ] Statistical analysis plan<br>[ ] Results |
| **Last Edited**<br>13/01/2010 | **Condition category**<br>Oral Health | [ ] Individual participant data<br>[ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Not Specified

## 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(s)
Tooth eruption.

## Key secondary outcome(s))
Not provided at time of registration

## Completion date
01/01/2005

**Reason abandoned (if study stopped)**
Participant recruitment issue

# Eligibility

**Key inclusion criteria**
Children.

**Participant type(s)**
Patient

**Healthy volunteers allowed**
No

**Age group**
Child

**Sex**
Not Specified

**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**
United Kingdom

England

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

# Sponsor information

**Organisation**

Department of Health (UK)

# Funder(s)

**Funder type**
Government

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

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration