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

Submission date 12/09/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 12/09/2003	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 13/01/2010	**Condition category** Oral Health	[ ] Individual participant data [ ] 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

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