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The iMAC Trial (Management of impacted MAxillary Central incisors)

Submission date
06/06/2022

Recruitment status
No longer recruiting

Registration date
16/06/2022

Overall study status
Completed

Last Edited
04/07/2022

Condition category
Oral Health

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Failure of a front tooth in the top jaw to erupt is a common problem in young children, affecting approximately 3% of the population. This can result in a disturbance in dental development, spacing between the teeth, an unattractive smile, and a compromise in aesthetics. The impact of not having a front tooth in the top jaw present can cause a negative impact on a child's self-esteem, social interaction, and potentially predispose a child to bullying episodes. In about 50% of cases in the United Kingdom, the cause for the failure of the front tooth to erupt into its normal position is the presence of an extra tooth. In this situation, it is unlikely that the top front tooth will erupt spontaneously hence increasing the need for complex and costly multidisciplinary treatment.

Treatments considered in this clinical situation are either removing the extra tooth and allowing the front tooth to spontaneously erupt or removing the extra tooth, surgical uncovering and bonding of a gold chain to the front tooth and using an orthodontic brace to align the tooth.

The disadvantages of the first approach are that the time taken for the tooth to erupt is very variable and it may erupt into a malaligned position, hence requiring further treatment. The second approach is associated with more predictability in terms of the time taken to align the tooth but may result in possible unesthetic alteration of the natural gumline. The current evidence base for best practice is poor. The measurement of outcomes important to patients affected by this condition is also lacking.

This study, which will be carried out at NHS sites, aims to investigate the success of top front tooth eruption following removal of the extra tooth with and without immediate application of orthodontic brace forces.

Who can participate?
Children aged between 8-10.5 years old (up to 6 months after the day after their 10th birthday) who present with failure of a front tooth in the top jaw to erupt on one side of the mouth due to the presence of an extra tooth, but are otherwise fit and well with good oral hygiene.

What does the study involve?
Following informed consent, study participants will be allocated for routine orthodontic treatment with a fixed appliance (0.022 x 0.028-inch slot size). A conventional upper sectional fixed appliance and mechanics will be utilised to open sufficient space within the dental arch to accommodate the unerupted maxillary central incisor tooth. An upper sectional fixed appliance will be used to create the required space utilising nickel titanium open coil spring placed on a 0.018-inch stainless steel archwire. Prior to surgery, the created space will be maintained using closed coil placed spring in the space on a 0.018-inch stainless steel archwire. This should be equivalent to the mesio-distal width of the erupted contralateral maxillary central incisor. Following this participant will be randomised into two treatment groups using allocation concealment: Surgical removal of the supernumerary tooth, gold chain bonding and immediate post-surgical orthodontic traction (Group 1); or Surgical removal of the supernumerary tooth only and monitoring eruption of the unerupted incisor for a period of 6 months (Group 2).

In Group 1, immediate application of piggyback orthodontic mechanics (0.014-inch Nickel titanium or elastomerics and 0.018-inch stainless steel archwires) will be employed to erupt the tooth. Following eruption of the incisal edge of the unerupted maxillary central incisor through the gingival mucosa, an attachment/ orthodontic bracket will be placed to the clinical crown to facilitate final orthodontic alignment of this tooth. Piggyback mechanics (0.014-inch nickel titanium or elastomerics and 0.018-inch stainless steel archwires) will then be employed again to further erupt the tooth. In Group 2, the eruption of the unerupted maxillary central incisor will be monitored and observed for 6 months. During this observation period, following eruption of the incisal edge of the unerupted maxillary central incisor through the gingival mucosa an attachment/ orthodontic bracket will be placed to the clinical crown to facilitate final orthodontic alignment of this tooth. Piggyback mechanics (0.014-inch Nickel titanium or elastomerics and 0.018-inch stainless steel archwires) will then be employed again to further erupt the tooth. In both groups, once the unerupted maxillary central incisor has been aligned to correct occlusal level compared to contra-lateral maxillary central incisor and an upper 0.019 x 0.025-inch stainless steel archwire will be ligated. As with any routine orthodontic treatment, patients will be encouraged to attend on a regular basis for adjustment of the appliance and monitoring of treatment progress.

In either Group 1 or Group 2, if after 6 months following removal of the supernumerary tooth the central incisor has failed to erupt, records (intra-oral photographs, study models and radiographs) will be taken. Following these records, a clinical decision will be made to either to continue monitoring the eruption of the incisor, arrange further surgical intervention or to apply piggyback orthodontic mechanics (0.014-inch Nickel titanium or elastomerics and 0.018-inch stainless steel archwires) to erupt the tooth.

Data will be collected at five time-points: (T0) Pre-treatment (Baseline) records: dental study casts, extra and intra oral photographs, radiographs, completion of Quality of life questionnaire and patient demographics) and participant demographics; (T1) Prior to randomisation to either surgical removal of the supernumerary tooth, gold chain bonding and immediate post-surgical orthodontic traction (Group 1); or Surgical removal of the supernumerary tooth and monitoring eruption of the unerupted incisor for a period of 6 months (Group 2): Intra oral photographs; (T2) Following eruption of the incisal edge of the unerupted maxillary central incisor through the gingival mucosa: dental study casts, extra and intra oral photographs; (T3) Unerupted maxillary central incisor aligned to correct occlusal level compared to contra-lateral maxillary central incisor: dental study casts, extra and intra oral photographs and completion of Oral Health-Related Quality of Life questionnaire; (T4) Three-months post-treatment: dental study casts, extra and intra oral photographs, and completion of Oral Health-Related Quality of Life questionnaire.

All data will be collected by the dental care team at the recruitment sites and at participants routine orthodontic appointments. The Oral Health-Related Quality of Life questionnaire (8-10 year olds) to be used in this trial is a previously validated instrument which has been used reliably in the United Kingdom population. In either intervention group if after the observation period of 6 months following removal of the supernumerary tooth the central incisor has failed to erupt, the following records will be taken: intra-oral photographs, study models and radiographs.

What are the possible benefits and risks of participating?
Participants enrolled into this study will contribute to the establishment of future treatment guidelines based on high quality evidence, development of efficient treatment protocols and high-quality patient outcomes. No serious adverse events (SAE) are expected to occur as part of this trial. Participants enrolled in the trial will be undergoing routine orthodontic treatment within the orthodontic departments of each recruitment site and this treatment does not differ from any other patients that are treated in the respective departments.

Where is the study run from?
Kings College London (UK) and Guys and St Thomas NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
From June 2022 to April 2025

Who is funding the study?
British Orthodontic Society Foundation (UK). This is an investigator-initiated and investigator-led trial. The funder of the trial has no role in trial design, data collection, data analysis, or data interpretation.

Who is the main contact?
1. Professor Martyn Cobourne (Chief investigator)
2. Mr Jadbinder Seehra, jadbinderpal.seehra@kcl.ac.uk (Investigator and PhD student)

Contact information

Type(s)
Scientific

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Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
280185

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52161, IRAS 280185

Study information

Scientific Title
Management of impacted maxillary central incisors: a multicentre randomised clinical trial

Acronym
iMAC

Study objectives
There will be no difference in the prevalence of successfully erupted permanent incisors at 6 months following either orthodontic space opening and removal of the supernumerary tooth only or orthodontic space opening, removal of the supernumerary tooth, bonding of a gold chain attachment followed by immediate post-surgical orthodontic traction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/03/2022, North West – Greater Manchester (GM) West (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048384; gmwest.rec@hra.nhs.uk), ref: 22 /NW/0062

Study design
Randomized parallel-group controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Unerupted (impacted) maxillary incisor teeth with associated supernumerary tooth

Interventions
This is a multicentre randomised clinical trial consisting of two parallel groups with equal randomisation to detect the superiority of one intervention over the other.

Randomization of the participants to one or the two groups will be undertaken to ensure unrestricted equal participant allocation (1:1). This process will be undertaken centrally (https://ctu.co.uk/randomisation/) to ensure random allocation and concealment.

Potential participants and their parents will be provided with both written study information leaflets and be given a verbal explanation of the study by the clinician/consultant at each recruitment site. Following informed consent, study participants will be allocated for routine orthodontic treatment with a fixed appliance (3M Unitek, Victory Series). A conventional sectional fixed appliance (orthodontic brace) and mechanics will be utilised to open sufficient space within the dental arch to accommodate the unerupted maxillary central incisor tooth (top front tooth). Patients will be seen at 4-6 week intervals for the routine adjustment of their fixed appliance.

The upper sectional fixed appliance will be used to create the required space utilising nickel titanium open coil spring placed on a 0.018-inch stainless steel archwire. Prior to surgery, the created space will be maintained using closed coil placed spring in the space on a 0.018-inch stainless steel archwire. This should be equivalent to the mesio-distal width of the erupted contralateral maxillary central incisor. Following this participants will be randomised into two treatment groups using allocation concealment:
1. Surgical removal of the supernumerary tooth (obstruction), gold chain bonding and immediate

post-surgical orthodontic traction (Group 1)
2. Surgical removal of the supernumerary (obstruction) tooth only and monitoring eruption of the unerupted incisor for a period of 6 months (Group 2)
In both groups any retained primary teeth in the upper arch will also be removed if indicated.

Data collection will take place at five time-points:
1. T0: Pre-treatment (Baseline) records (dental study casts, extra- and intra-oral photographs, radiographs, and completion of Quality of life questionnaire) and participant demographics
2. T1 (intra-oral photographs): Prior to randomisation to either surgical removal of the supernumerary tooth, gold chain bonding and immediate post-surgical orthodontic traction (Group 1) or surgical removal of the supernumerary tooth and monitoring eruption of the unerupted incisor for a period of 6 months (Group 2)
3. T2 (dental study casts, extra- and intra-oral photographs): In Group 1 (Surgical removal of the supernumerary tooth, gold chain bonding, and immediate post-surgical orthodontic traction) immediate application of piggyback orthodontic mechanics (0.014-inch Nickel titanium or elastomerics and 0.018-inch stainless steel archwires) will be employed to erupt the tooth. Following the eruption of the incisal edge of the unerupted maxillary central incisor through the gingival mucosa, an attachment/orthodontic bracket will be placed to the clinical crown to facilitate the final orthodontic alignment of this tooth. Piggyback mechanics (0.014-inch nickel titanium or elastomerics and 0.018-inch stainless steel archwires) will then be employed again to further erupt the tooth. In Group 2 (Surgical removal of the supernumerary tooth only and monitoring eruption of the unerupted incisor for a period of 6 months) the eruption of the unerupted maxillary central incisor will be monitored and observed for 6 months. Following the eruption of the incisal edge of the unerupted maxillary central incisor through the gingival mucosa, an attachment/orthodontic bracket will be placed to the clinical crown to facilitate the final orthodontic alignment of this tooth. Piggyback mechanics (0.014-inch Nickel titanium or elastomerics and 0.018-inch stainless steel archwires) will then be employed again to further erupt the tooth; or in either Group 1 or Group 2 if after 6 months following removal of the supernumerary tooth the central incisor has failed to erupt, records (intra-oral photographs, study models and radiographs) will be taken. Following these records, a clinical decision will be made to either continue monitoring the eruption of the incisor, arrange further surgical intervention or to apply piggyback orthodontic mechanics (0.014-inch Nickel titanium or elastomerics and 0.018-inch stainless steel archwires) to erupt the tooth.
4. T3 (dental study casts, extra- and intra-oral photographs and completion of Quality of life questionnaire): Unerupted maxillary central incisor aligned to correct occlusal level compared to contra-lateral maxillary central incisor and an upper 0.019 x 0.025-inch stainless steel archwire has been ligated
5. T4 (dental study casts, extra- and intra-oral photographs, and completion of Quality of life questionnaire): Three months post-treatment (top brace has been removed).

Intervention Type
Procedure/Surgery

Primary outcome measure
Prevalence of successfully erupted permanent maxillary incisors (top front tooth) following removal of the supernumerary tooth (obstruction) measured using clinical assessment of intra-oral photographs at baseline and 6 months. The successful eruption will be defined as the eruption (successful outcome) of the unerupted maxillary central through the gingival mucosa during the 6-month observation period. Clinically, the amount of clinical crown visible should allow the placement of an orthodontic attachment or removal of the bonded gold chain attachment and placement of an orthodontic attachment/bracket.

Secondary outcome measures
1. Effect of initial tooth position on time taken for the tooth to erupt measured using radiography to assess initial tooth position at baseline and time to eruption (as defined above) using assessment of the pretreatment orthopantomogram radiographic image taken at baseline and the time (days) taken for the tooth to erupt (T2) through observation for up to 6 months.
2. Time taken to align the unerupted tooth to the correct occlusal position measured as time to correct occlusal position assessed using observation for up to 6 months to calculate the time (days) between T2 (successful eruption of the maxillary incisor tooth at 6 months post-supernumerary removal) and T3 (correct occlusal position of the unerupted incisor tooth).
3. Gingival (gum line) aesthetics measured using a rating of crown length using a visual analog scale (VAS) and subjective judgments relating to the appearance of the operated maxillary central incisor by two groups of judges (layperson and professional) to assess intra-oral photographs taken at 3 months post-orthodontic appliance removal
4. Quality of Life measured using self-reported Oral Health Related-Quality of Life (OHRQoL) at baseline, 6, and 9 months

Overall study start date
01/11/2021

Completion date
01/04/2025

Eligibility

Key inclusion criteria
1. Aged between 8-10.5 (6 months to the day after their 10th birthday) years
2. Fit and well
3. Good oral hygiene
4. Present with the Unilateral impaction of an upper maxillary central incisor due to the presence of a (supernumerary) tooth
5. In the mixed dentition with eruption of upper 6’s, single maxillary central incisor and lateral incisors
6. Parents able to give informed consent

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
10.5 Years

Sex
Both

Target number of participants

Planned Sample Size: 92; UK Sample Size: 92

Key exclusion criteria
1. History of previous orthodontic treatment
2. Presence of an impacted maxillary incisor due to root dilaceration/unfavourable morphology
3. Participants participating in other trials or studies
4. Participants with a history of nickel allergy
5. Participants who decline to take part in the study

Date of first enrolment
31/07/2022

Date of final enrolment
01/04/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Maxillofacial Unit, William Harvey Hospital
Kennington Rd
Willesborough
Ashford
United Kingdom
TN24 0LZ

Study participating centre
Department of Orthodontics, Kings College Hospital NHS Foundation Trust
Bessemer Road
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United Kingdom
SE5 9RS

Study participating centre
Orthodontic Department, St Luke’s Hospital
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Study participating centre
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Study participating centre
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United Kingdom
S10 2TA

Study participating centre
Royal United Hospitals
Combe Park
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United Kingdom
BA1 3NG

Study participating centre
Child Dental Health, Bristol Dental School
Lower Maudlin St
Bristol
United Kingdom
BS1 2LY

Study participating centre
Orthodontic Department, Stoke Mandeville Hospital
Aylesbury
United Kingdom
HP17 8UZ

Study participating centre
Guys Hospital
Guys Hospital
Great Maze Pond

London
United Kingdom
SE1 9RT

Sponsor information

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reza.razavi@kcl.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
Tower Wing
Great Maze Pond
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Telephone contact number not provided
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Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/Home.aspx

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
British Orthodontic Society Foundation

Alternative Name(s)
BOS Foundation, BOSF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The chief investigator, PhD student or treating dental care team (research team) at each recruitment site will inform the patients about the study findings after the trial ends. A summary sheet regarding the results of the study will be provided. The reporting of this trial will be in accordance with the CONSORT guidelines. The results of the study will be disseminated via appropriate scientific publication (peer-reviewed journals) and presentations at conferences /meeting. Additionally, a printed copy of the accepted scientific publication following completion of the study will be posted to each participant (optional). The use of professional writers will not be employed. The protocol will be published on a publicly accessible database, ISRCTN registry (https://www.isrctn.com/).

Intention to publish date
01/10/2025

Individual participant data (IPD) sharing plan
The full anonymized dataset of the trial will be made openly available through Zenodo (https://zenodo.org/).

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Child/Young Person Information Sheet version 2	10/03/2022	06/06/2022	No	Yes
Participant information sheet	Parent/Guardian Information Sheet version 2	10/03/2022	06/06/2022	No	Yes
HRA research summary			28/06/2023	No	No