

# The iMAC Trial (Management of impacted Maxillary Central incisors)

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
06/06/2022	Recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
16/06/2022	Ongoing	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
30/10/2025	Oral Health	<input checked="" type="checkbox"/> 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 8-12.0 years old (up to the day before their 13th 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 December 2027

**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](mailto:jadbinderpal.seehra@kcl.ac.uk) (Investigator and PhD student)

## Contact information

### Type(s)

Scientific

### Contact name

Mr Jadbinder Seehra

### Contact details

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### Type(s)

**Principal investigator**

**Contact name**

Prof Martyn Cobourne

**ORCID ID**

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**Contact details**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

280185

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)**

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.

### **Key secondary outcome(s)**

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

**Completion date**

31/12/2027

## Eligibility

**Key inclusion criteria**

Current key inclusion criteria as of 30/10/2025:

1. Aged between 8-12 (up to the day before their 13th 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

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Previous 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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

8 years

**Upper age limit**

12 years

**Sex**

All

**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**

31/12/2027

## Locations

**Countries of recruitment**

United Kingdom

England

**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

London

United Kingdom

SE5 9RS

**Study participating centre**

**Orthodontic Department, St Luke's Hospital**

Little Horton Lane

Bradford  
United Kingdom  
BD5 0NA

**Study participating centre**  
**Orthodontic Department, Pinderfields Hospital**  
Aberford Road  
Wakefield  
United Kingdom  
WF1 4DG

**Study participating centre**  
**Academic Unit of Oral Health and Development**  
School of Clinical Dentistry  
Sheffield  
United Kingdom  
S10 2TA

**Study participating centre**  
**Royal United Hospitals**  
Combe Park  
Bath  
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

**Organisation**  
King's College London

**ROR**  
<https://ror.org/0220mzb33>

**Organisation**  
Guy's and St Thomas' NHS Foundation Trust

**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

## 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Child/Young Person Information Sheet version 2	10/03/2022	06/06/2022	No	Yes
<a href="#">Participant information sheet</a>	Parent/Guardian Information Sheet version 2	10/03/2022	06/06/2022	No	Yes
<a href="#">Participant information sheet</a>	Child/Young Person Information Sheet version 3	18/03/2025	30/10/2025	No	Yes
<a href="#">Participant information sheet</a>	Parent/Guardian Information Sheet version 3	18/03/2025	30/10/2025	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes