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Comparison of two screws for maxillary expansion in prepubertal children

Submission date
04/10/2016

Recruitment status
No longer recruiting

Registration date
08/11/2016

Overall study status
Completed

Last Edited
04/01/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The dental arches are the two arches of teeth, one on each jaw (upper and lower arch). A posterior crossbite is a misalignment of the teeth that occurs when the upper arch and/or the upper jaw are narrower than the lower arch, and can happen on one (unilateral) or both (bilateral) sides of the mouth. Treatment of a posterior crossbite usually involves expanding the upper arch with either a fixed or removable orthodontic appliance (brace). Expansion with fixed expanders may be more successful than removable expansion plates at correcting posterior crossbites in children. Growing patients may report undesirable side effects during the expansion phase with fixed expanders, such as pain and mouth ulcers. Pain could be reduced by modifying the amount of force applied during the expansion. It is not known whether an expansion screw that uses moderate and continuous force could cause less pain compared with a standard screw that uses heavy and intermittent force. The aim of this study is to compare the effectiveness and side effects of a screw for maxillary expansion that uses moderate and continuous force with a standard expansion screw that uses heavy and intermittent force.

Who can participate?
Children aged between 6 and 14 with a posterior crossbite

What does the study involve?
Participants are randomly allocated to be treated with one of two types of rapid maxillary expanders, either with an expansion screw that uses moderate and continuous force or a standard expansion screw that uses heavy and intermittent force. Participants are followed-up every 2 weeks during the active phase of expansion (about 3 months) and then they are checked every month until the completion of the study (1 year after the start of treatment).

What are the possible benefits and risks of participating?
Participants may benefit from correction of their posterior crossbite. The possible risks include pain and mouth ulcers.

Where is the study run from?
1. University of Florence (Italy)
2. University of Rome Tor Vergata (Italy)

When is the study starting and how long is it expected to run for?
January 2016 to September 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Lorenzo Franchi
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LF1

Study information

Scientific Title
Comparison of two screws for maxillary expansion in prepubertal children: a multicenter randomized controlled trial

Study objectives

The objective of this randomized controlled trial (RCT) is to compare the efficacy and side effects of a screw for maxillary expansion that uses moderate and continuous forces (test) and a standard expansion screw that uses heavy and intermittent forces (control).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pediatric Ethics Committee of the Meyer Paediatric Hospital, 29/04/2016, ref: 57/2016

Study design
Three-centered superior parallel two-group randomized clinical trial with balanced randomization and blind examiner

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Maxillary arch constriction

Interventions
Patients will be randomized to receive a screw for maxillary expansion that uses moderate and continuous forces (Memoria Leaf Spring Activated Expander A2704, Leone SpA) (test) or a standard expansion screw that uses heavy and intermittent forces (Rapid Expander with Telescopic Guides A2620, Leone SpA) (control).

Randomisation: Computer-generated, balanced, with allocation concealment by opaque sequentially numbered sealed envelopes.

The test expander will be activated by the operators every 2 weeks. The control expander will be activated (1/4 of a turn) by the parents of the patients every day. Patients will be followed-up every 2 weeks during the active phase of expansion (about 3 months) and then they will be checked every month until the completion of the study (1 year after the start of treatment).

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Maxillary intermolar width, measured at baseline and at one-year follow-up
2. Pain, measured using a visual analogue scale (VAS) for the first 12 weeks (a total of 12 questionnaires)

Secondary outcome measures
1. Difficulties in speaking, measured using VAS every week for the first 12 weeks (a total of 12 questionnaires)
2. Difficulties in keeping the expander clean, measured using VAS every week for the first 12 weeks (a total of 12 questionnaires)
3. Treatment satisfaction of both the patients and the patients' parents, evaluated at one-year follow up
4. Complications, recorded during the 1-year follow up period
5. Variables either on dental casts or postero-anterior cephalograms, measured at baseline and at one-year follow up

Overall study start date
06/01/2016

Completion date
30/11/2019

Eligibility

Key inclusion criteria
1. Children in prepubertal stage (age between 6 and 14 years)
2. Negative posterior transverse discrepancy of at least 3 mm eligible for maxillary expansion
2. The first molars should be erupted with a mixed dentition stage in early transitional period or inter-transitional period

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
56 (28 per centre)

Total final enrolment
56

Key exclusion criteria
1. Age older than 14 years or younger than 6 years
2. Deciduous dentition or mixed dentition in the late transitional period or permanent dentition
3. Maturation stage of cervical vertebrae CS3 or greater
4. Agenesis of maxillary second premolars
5. Periodontal disease
6. Neurologic or systemic disease
7. Allergy to nickel
8. Cleft lip and/or palate
9. Patients irradiated in the neck-head area
10. Chemo- or immune-therapy in the previous 5 years

Date of first enrolment
05/09/2016

Date of final enrolment
22/11/2018

Locations

Countries of recruitment
Italy

Study participating centre
University of Florence
Department of Surgery and Translational Medicine
Italy
50127

Study participating centre
University of Rome Tor Vergata
Department of Clinical Sciences and Medicine
Italy
00133

Sponsor information

Organisation
Leone Orthodontics and Implantology

Sponsor details
Via P. a Quaracchi, 50
Sesto Fiorentino (Firenze)

Italy
50019

Sponsor type
Industry

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Lorenzo Franchi (lorenzo.franchi@unifi.it)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/11/2020	23/11/2020	Yes	No
Results article		11/06/2021	14/06/2021	Yes	No
Results article		03/01/2024	04/01/2024	Yes	No