

# Comparison of two screws for maxillary expansion in prepubertal children

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<b>Registration date</b> 08/11/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/01/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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  
lorenzo.franchi@unifi.it

## Contact information

### Type(s)

Public

### Contact name

Dr Lorenzo Franchi

### ORCID ID

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## Additional identifiers

### Protocol serial number

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)

## **Study design**

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

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **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(s)**

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)

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

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

## **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

## Healthy volunteers allowed

No

## Age group

Child

## Lower age limit

6 years

## Upper age limit

14 years

## Sex

All

## 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

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**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?
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<a href="#">Results article</a>	results	20/11/2020	23/11/2020	Yes	No
<a href="#">Results article</a>		11/06/2021	14/06/2021	Yes	No
<a href="#">Results article</a>		03/01/2024	04/01/2024	Yes	No