

Chewing ability and pain in patients with Primary Failure of Eruption (PFE)

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Objectively evaluate the chewing ability with the mixing ability test and evaluation of complaints with validated questionnaires, compared to gender and aged matched control group.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON57468

Source

ToetsingOnline

Brief title

Chewing ability and pain in patients with Primary Failure of Eruption (PFE)

Condition

- Other condition

Synonym

failure of changing teeth/molars, tooth eruption problem

Health condition

maxillofaciale aandoeningen, mogelijk congenitaal

Research involving

Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chewing, dentition, pain, PFE

Outcome measures

Primary outcome

Identification of functional and aesthetic burden in PFE patients, pilot study
for baseline parameters in further research

Secondary outcome

NA

Study description

Background summary

Primary failure of eruption (PFE) is a rare condition characterized by non-syndromic eruption failure of primary or secondary teeth in the absence of a mechanical obstruction. Little is known about PFE. Because of the rareness of the condition, prevalence of 0.06% (Hanisch e.a. 2018), no large studies have been reported.

Posterior teeth are mostly affected, resulting in a dorsal open bite which can lead to functional problems such as inability to chew or aesthetic impairment in most severe cases. It can occur in one or multiple dental quadrants. No studies have been performed regarding patient reported outcomes and chewing ability. Treatment is limited due to tooth mobility problems as soon as braces are placed, resulting in ankylosis.

It is hypothesised that patients with PFE experience more problems with chewing, which can result in Temporal Mandibular Joint problems/pain and limitations in the type of food that can be consumed.

Study objective

Objectively evaluate the chewing ability with the mixing ability test and evaluation of complaints with validated questionnaires, compared to gender and

aged matched control group.

Study design

A pilot study with 10 patients with known PFE and 10 control subjects (gender and age matched).

Study burden and risks

There is a limited burden since the requested information will be obtained during 1 visit. There are no risks associated to the questionnaires. There is a neglectable risk associated with the chewing ability test (for example: accidental swallowing of the wax tablet, with no clinical consequences). There is no direct benefit to the individual participants. There is an expected potential benefit for new patients as this pilot study can lead to further insight in functional (and aesthetic) problems in this rare condition and subsequently specific treatment can be adjusted accordingly.

Amsterdam UMC is a designated centre for multidisciplinary advice for PFE (combined consultation with Maxillofacial Surgeon, Maxillofacial Prosthetic Dentist and Orthodontist). Therefore, the limited patients that are suffering from this condition are already known in this centre and next step treatment options are desired.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (16-17 years)

Adults (18-64 years)

Inclusion criteria

age and gender matched

Exclusion criteria

other maxillofacial condition or previous surgery

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Registration: No

Ethics review

Approved WMO

Date: 18-04-2025

Application type: First submission

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84305.018.23