

Invisalign - a concept for the prevention of white spot lesions in teenaged orthodontic patients?

Submission date 03/09/2014	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 16/10/2014	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 16/10/2014	Condition category Oral Health	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Wire dental braces (fixed vestibular multi-bracket appliances) are traditionally considered to be the best treatment (gold standard) for correcting misaligned teeth (dental malocclusion) in teenage patients. However, patients wearing wire braces are 5 times more likely to develop dental cavities (caries) and white spot lesions (often an early sign of tooth decay) than people who don't. Such damage to the teeth cannot be reversed. Invisalign is an alternative to the wire brace. It is made out of plastic, using transparent aligners to gradually adjust the affected teeth. It is often used by people who have misaligned teeth but want a more attractive solution to wearing the traditional brace. Here, we want to find out whether wearing Invisalign rather than wire dental braces will result in fewer or more white spot lesions after 6 months and then after 12 months of therapy.

Who can participate?

Patients aged between 13-19 years needing dental (orthodontic) treatment to correct misaligned teeth.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 are treated with a traditional multi-bracket appliance for orthodontic treatment. Those in group 2 receive Invisalign therapy. All participants are examined for white spot lesions at the start of the study, after 6 months of orthodontic treatment, and then after 12 months of treatment.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Department of Orthodontics, University Hospital Freiburg (Germany)

When is the study starting and how long is it expected to run for?

November 2014 to October 2016

Who is funding the study?
International Align Research Award of the Align Technology, North America (USA)

Who is the main contact?
Professor Britta A. Jung

Contact information

Type(s)
Scientific

Contact name
Prof Britta A. Jung

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Additional identifiers

Study information

Scientific Title
Invisalign - a concept for the prevention of white spot lesions in teenaged orthodontic patients?
A prospective controlled clinical trial

Study objectives
The aim of this study is to investigate the incidence of white spot lesions during orthodontic treatment with Invisalign and multi-bracket appliance treatment (the gold standard) in teenaged patients.
The null hypothesis of no difference in the incidence of white spot lesions between teeth undergoing treatment with fixed braces and Invisalign therapy will be investigated. The investigation will be designed as a prospective, bicenter controlled clinical study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Albert-Ludwigs-University of Freiburg, Germany (Ref. No: 406/14 (MPG§23))

Primary study design
Interventional

Study design

A prospective controlled clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malocclusion

Interventions

Two groups of patients (male and female, aged 13-19 years) will be randomly allocated into one of two arms:

1. Group 1 will consist of 30 patients. All of these patients receive a traditional multi-bracket appliance for orthodontic treatment.
2. Group 2 will consist of 30 patients. All of these patients receive Invisalign therapy for orthodontic treatment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Macroscopic characterization (presence, frequency, and severity) of white spot lesions at baseline, after 6 months, and after 12 months of orthodontic treatment. The severity of disease will be rated according to Gorelick's classification:

Grade 0: no visible white spot lesions on clinical investigation

Grade 1: minor white spot lesions

Grade 2: severe white spot lesions

Grade 3: white spot lesions with cavitation

2. Determination of fluorescence, size and lesion depth and the bacterial activity of white spot lesions by means of quantitative light-induced fluorescence measurement (QLF) at baseline, after 6 months, and after 12 months of orthodontic treatment.

Key secondary outcome(s)

Determination of fluorescence, size and lesion depth and the bacterial activity of white spot lesions by means of quantitative light-induced fluorescence measurement (QLF) after active orthodontic treatment and 6 month later.

Completion date

01/10/2016

Eligibility

Key inclusion criteria

1. Orthodontic indication for a vestibular multi-bracket appliance or
2. The need and desire to receive Invisalign therapy
3. Persons aged 13-19 years (teenagers) with fully erupted and visible teeth before treatment

4. No white spot lesions at baseline/no caries
5. Good oral hygiene
6. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

13 Years

Upper age limit

19 Years

Sex

All

Key exclusion criteria

1. Patients with cheilognathopalatoschisis or other syndromes associated with craniofacial abnormalities
2. Patients with enamel abnormalities

Date of first enrolment

01/11/2014

Date of final enrolment

01/10/2016

Locations**Countries of recruitment**

Germany

Study participating centre

Head of the Department of Orthodontics

Freiburg, Germany

Germany

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Sponsor information

Organisation

Align Technology, Inc. (USA)

ROR

<https://ror.org/005sbaa41>

Funder(s)**Funder type**

Industry

Funder Name

International Align Research Award of the Align Technology, North America (USA)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration