

Treatment of permanent front teeth affected by hypomineralisation (white and yellow spots)

Submission date 17/02/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/05/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/05/2022	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Hypomineralisation is a condition that affects the outer layer (enamel) of the teeth and can cause creamy/white/yellow/brown spots, enamel breakdown and tooth hypersensitivity. Hypersensitivity impairs tooth brushing and increases the risk of tooth decay. Resin infiltration treatment can improve the appearance of the teeth. This study aims to evaluate the effectiveness of resin infiltration in permanent incisors (front teeth) with yellow and white spots that are affected by hypomineralization.

Who can participate?

Children aged 6 to 16 years who have permanent incisors affected by hypomineralization with white and yellow spots

What does the study involve?

Chosen teeth are randomly allocated into two groups for one or multiple cycles of resin infiltration treatment. All teeth are assessed immediately and at 3 months after treatment.

What are the possible benefits and risks of participating?

There are no known risks to participants as any failed treatment will be redone using another method.

Where is the study run from?

Tishreen University (Syria)

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

January 2022 to July 2022

Who is funding the study?

Tishreen University (Syria)

Who is the main contact?

1. Dr Nabih Raslan, raslan.nabih@tishreen.edu.sy
2. Mr Shams Alghawe, shams123490@gmail.com

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

2654

Study information

Scientific Title

Management of permanent incisor affected by hypomineralisation using resin infiltration

Study objectives

Using icon etch (hcl) several times can improve cosmetic appearance more than using it once

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/05/2019, institutional review board of Tishreen University (Latakia, PO Box 2230, Syria; Tel: not available; dean.dentist@tishreen.edu.sy), ref: 2654

Study design

Interventional double-blind two-arm randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Molar incisor hypomineralisation

Interventions

Participants are randomly allocated to either group A and group B using a random table. Group A is treated with Icon Etch for several cycles until a positive ethanol test is reached, not to exceed 3 cycles, whereas group B is treated with Icon Etch once. Participants are asked to attend a follow-up examination with clinical evaluation at 3 months post-treatment.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Full or partial positive spot coverage measured using a coverage scale immediately after treatment
2. Parent's satisfaction measured using a Likert scale immediately after treatment

Key secondary outcome(s)

Lesion color measured using the easysshade Compact device before and immediately after treatment and after 3 months

Completion date

01/07/2022

Eligibility

Key inclusion criteria

1. Children who have permanent incisor with opacities
2. Aged 6 to 16 years

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

16 years

Sex

All

Key exclusion criteria

1. Children with signs of fluorosis, tetracycline staining, amelogenesis imperfecta, or generalized enamel hypoplasia
2. Undergoing orthodontic treatment
3. Opacities confined to the incisors only
4. Absence of parental consent to participate

Date of first enrolment

20/02/2022

Date of final enrolment

20/05/2022

Locations

Countries of recruitment

Syria

Study participating centre

Tishreen University

Faculty of Dentistry

Latakia

Syria

00963

Sponsor information

Organisation

Tishreen University

ROR

<https://ror.org/04nqts970>

Funder(s)

Funder type

University/education

Funder Name

Tishreen University

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Nabih Raslan (raslan.nabih@tishreen.edu.sy), from 3 months after publication up to 3 years. Data will be available for researchers who provide a methodological sound proposal.

IPD sharing plan summary

Available on request