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

Submission date
17/02/2022

Recruitment status
No longer recruiting

Registration date
04/05/2022

Overall study status
Completed

Last Edited
04/05/2022

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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@tishren.edu.sy
2. Mr Shams Alghawe, shams123490@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
Lesion color measured using the easyshade Compact device before and immediately after treatment and after 3 months

Overall study start date
20/01/2022

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

Age group
Child

Lower age limit
6 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
30

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
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Sponsor information

Organisation
Tishreen University

Sponsor details

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Sponsor type
University/education

Website
http://en.tishreen.edu.sy/

ROR
https://ror.org/04nqts970

Funder(s)

Funder type
University/education

Funder Name
Tishreen University

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2022

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