ISRCTN16862566 https://doi.org/10.1186/ISRCTN16862566

Taste acceptance of fluoride varnish on autistic patients

Submission date
20/02/2025

Recruitment status
No longer recruiting

Registration date
01/03/2025

Overall study status
Completed

Last Edited
11/03/2025

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People with autism spectrum disorder (ASD) are known to have difficulties with social communication and interactions and have different perceptions of the world. Maintaining oral hygiene and a healthy diet can be challenging in autistic patients and so they are at high risk of dental caries (tooth decay). Fluoride varnish is usually applied to both permanent and primary teeth to prevent dental caries. Fluoride promotes remineralization and prevents demineralization of teeth. Duraphat varnish is the most widely used fluoride varnish preparation in the UK and is the only product licensed as a prescription-only medicine specifically for caries prevention. There are other fluoride varnishes with different flavours which are available on the market but are unlicensed for caries prevention, despite having the same content of fluoride as in Duraphat. However, these fluoride varnishes have different formulations to enhance the ability of fluoride. Several studies have highlighted differences among different fluoride varnishes in terms of the amount of initial fluoride release, fluoride uptake by enamel and cumulative fluoride release over time. These studies reported that other varnishes do release more fluoride ions than Duraphat varnish. Most dental professionals use fluoride varnish off-label for the prevention of caries. Unfortunately, there is no unflavoured option to choose from which may be beneficial to these patients. There is no previous research on the investigation of taste perceptions of different flavoured fluoride varnishes in patients with ASD. The aim of this study is to investigate the acceptance of different flavoured fluoride varnish compared to Duraphat on young patients diagnosed with ASD only.

Who can participate?
Autistic children aged 3-15 years

What does the study involve?
Participants are randomly allocated to three groups. The first group will receive the banana-flavored Duraphat varnish, the second group receive strawberry-flavored MI varnish, and the third group will be applied with the cherry-flavored profluorid varnish. The participants' non-verbal behavior is measured.

What are the possible benefits and risks of participating?
The benefits would be to improve patients’ experience of dental visits and to prevent the

formation of tooth decay by the application of fluoride varnish on teeth. There are no risks involved.

Where is the study run from?
Community dental clinics of Port Talbot Centre (UK)

When is the study starting and how long is it expected to run for?
July 2018 to December 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Rohini Mohan, Rohini.mohan@wales.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
245291

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
19/WA/0033

Study information

Scientific Title

Quantitative analysis on the taste perception of different flavoured fluoride varnish on patients with autistic spectrum disorder (ASD)

Study objectives
To assess the taste acceptance of young patients with autistic traits to different flavoured fluoride varnishes

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/03/2019, Gwasanaeth Moeseg Ymchwil, Research Ethics Service, Wales Research Ethics Committee (Community Dental Services, Port Talbot Resource Centre, Port Talbot, SA12 7BJ, United Kingdom; +44 (0)1267 61 1164; Wales.REC6@wales.nhs.uk), ref: 19/WA/0033

Study design
Single-center interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community, Dental clinic

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Preventive dental care in autistic children

Interventions
The taste acceptance of the fluoride varnish compounds Duraphat® (Colgate, New York, NY, USA), Profluorid® (VOCO GmbH, Cuxhaven, Germany), and MI varnish® (GC Europe N.V., Leuven, Belgium) are investigated. The three varnish preparations were presented without labels because of their similar application methods. The Frankl behavior rating scale was used to measure the subjects' non-verbal behavior (objective data) as a measure of taste acceptance of three different fluoride varnishes, and a three-point smiley rating scale (subjective data) will be used to assess the subject's acceptance of the preparation. The intervention consists of three phases preceded by an initial phase where the procedure is explained and demonstrated to children in a standard dialogue by the project leader (X) using the Tell-Show-Do technique for behavior management. Later subjects are instructed and guided on how to indicate the taste of the FV preparation on the three-point smiley rating scale, which includes faces with a laughing, crying or neutral facial expression. The non-verbal behavior of each of the subjects will be

assessed before (phase I) and immediately after the FV application (phase II) by using the Frankl Behavior Rating Scale, ranging from ‘definitely negative’ to ‘definitely positive’. The nonverbal behavior of each subject before fluoride varnish application will be evaluated by the principal investigator (X) who is blinded to the allocation of participants. The dental nurse will assign the participants to the three FV interventions randomly with an allocation ratio of 1:1:1. Simple random allocation is used where each participant is randomly allocated to one of the three groups as they arrive. This method ensures that each participant has an equal chance of being assigned to any of the groups and concealed until the exact moment of assignment. Twenty participants are included in each of the three groups to allow for comparison of the three flavored fluoride varnishes. The first group will receive the banana-flavored Duraphat varnish, the second group receive strawberry-flavored MI varnish, and the third group will be applied with the cherry-flavored profluorid varnish. Fluoride varnish applications are performed by the principal investigator (X) who is a trained pediatric dental specialist. Two trained calibrated dentists who are blinded to the type of Varnish preparation and outcomes of the study will examine and evaluate the nonverbal behavior of each subject immediately after application using the Frankl Behavior Rating Scale. After the varnish application, each child will be additionally asked to choose the appropriate smiley face from the three-point smiley rating scale (phase III) which closely represents their evaluation of the taste of FV preparation received by them, while another interviewer (XX), who is blinded to the type of varnish used and study outcomes, will record the feedback from subjects.

Intervention Type
Behavioural

Primary outcome measure
(Negative or positive) non-verbal behavior measured using the Frankl behavior rating scale immediately after the application of fluoride varnish (Phase II)

Secondary outcome measures
1. Non-verbal behavior (subjective feedback) measured/collected using a three-point smiley rating scale after fluoride varnish application (after fluoride varnish application, each child was additionally asked to choose the appropriate smiley face from the three-point hedonic scale [phase III] which closely represents their evaluation of the taste of flavored fluoride varnish received by them)
2. Non-verbal behavior of each subject measured using the Frankl Behavior Rating Scale, before fluoride varnish application (Phase I)

Overall study start date
18/07/2018

Completion date
23/12/2023

Eligibility

Key inclusion criteria
1. 3-15-year-old autistic children
2. Children with previous or current caries experience who were indicated for fluoride varnish application based on caries risk assessment

Participant type(s)

Patient, Other

Age group
Child

Lower age limit
3 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Coexistence of diseases that may affect taste assessment (type 1 diabetes, infectious diseases
2. 2. Requiring antibiotic therapy, neoplastic diseases)
3. Oral thrush and injuries of the oral mucosa
4. Ulcerative gingival stomatitis
5. Lack of informed consent
6. Voluntary withdrawal of the parent or legal guardian at any stage of the procedure
7. Previous hospital admission for uncontrolled asthma
8. History of dental care provided in sedation or general anesthesia
9. Known sensitivity to colophony (Duraphat®, Profluorid®)
10. Milk protein or hydroxybenzoate allergy (MI varnish®)

Date of first enrolment
01/06/2019

Date of final enrolment
16/11/2022

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Community Dental Clinics
Port Talbot Resource Centre
Port Talbot

United Kingdom
SA12 7BJ

Sponsor information

Organisation
Abertawe Bro Morgannwg University Health Board

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-
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Sponsor type
University/education

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Dr Rohini Mohan, rohini.mohan@wales.nhs.uk (subject to the guidelines of the affiliated institution/university)
The type of data that will be shared: Consent form used in the study. The relevant results /findings of the study will be shared in the manuscript text to be considered for publication in a peer-reviewed journal.

Dates of availability: As and when the manuscript is published.
Whether consent from participants was required and obtained: Consent was obtained from the parents/legal guardians.
Comments on data anonymization: Data confidentiality maintained.
Any ethical or legal restrictions: None
Any additional comments: None

IPD sharing plan summary

Available on request