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Arrest of caries using different silver fluoride solutions in the Healthy Kids Cambodia project

Submission date
31/01/2019

Recruitment status
No longer recruiting

Registration date
07/02/2019

Overall study status
Completed

Last Edited
27/03/2023

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Children in Cambodia have a severe burden of dental caries (tooth decay) especially affecting the primary teeth. The average 6 year old Cambodian child has 9 cavitated teeth and 2.7 pulpally involved teeth. If the conventional treatment approach to address these problems (e.g. “drilling and filling” and extractions) was implemented, the costs would be more than the national health budget for Cambodia, and the whole dental workforce of Cambodia could still not provide all the treatment needed. In the case of the Healthy Kids Cambodia Strategy, Silver Fluoride treatments have been used since 2014 and are viewed as the best first step to slowing down or arrest the dental caries process among a population where the disease is ubiquitously severe. The main disadvantage of treatment with Sliver Fluoride solutions is that the cavitated carious lesions become a dark black colour which could potentially be stigmatising or unacceptable to children and their families. For that reason, it is important to explore ways in which we can achieve the most aesthetically favourable outcome. The addition of potassium iodide solution to the clinical procedure has been shown to improve aesthetic outcomes in other settings and so the aim of this study is to confirm whether or not this type of treatment can achieve the same results among Cambodian children.

Who can participate?
Children who are 7- to 10-years old, with one or more active carious lesions (cavities) in primary teeth not involving the pulp, and attending schools that are targeted to begin the Healthy Kids Cambodia Project during the 2018-2019 academic year

What does the study involve?
Participants are randomly allocated at the school level to one of four different Silver Fluoride treatments: Rivastar version 1 with and without potassium iodide (step 2), and Rivastar version 2 with and without step 2. This treatment is provided to children at the start of the study and at 6-month follow-up. The solutions are painted onto dry teeth using a small brush.

What are the possible benefits and risks of participating?
The benefits of participating are that cavities will become stable and children will experience a reduction in symptoms as a result of dental caries. The risks are that they may not like the aesthetic appearance of cavities that become a darker colour.

Where is the study run from?
University of Puthisastra, Phnom Penh (Cambodia)

When is the study starting and how long is it expected to run for?
October 2018 to March 2020

Who is funding the study?
SDI Limited

Who is the main contact?
Dr Bathsheba Turton
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
307NECHR

Study information

Scientific Title
Arrest of caries using different silver fluoride solutions in the Healthy Kids Cambodia project

Study objectives

1. Rivastar version 1 and version 2 have the same caries arrest rate
2. The addition of 'step 2' with potassium iodide will improve the aesthetic outcome

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Ethics Committee for Health Research, National Institute of Public Health, #80, Samdach Penh Nouth Blvd, Sangkat Boeungkok2, Khan Toul Kork, Phnom Penh, Tel: +855 (0) 12842442 / +855 (0)12528789 / +855 (0)12203382, Email: sarayvannat@gmail.com / nouthsarida@gmail.com, ref: 307NECHR

Study design
Four-arm parallel-design randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Treatment

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
Dental caries

Interventions
This is a four-armed, parallel-design randomized controlled trial that will follow the recommendations for Interventional Trials (SPIRIT) 2013 Statement. The study will include those children from four schools who were scheduled to join the HKC strategy in the 2019-2020 academic year, thus facilitating the early access to HKC interventions. Children will be randomized at school level for allocation into the four treatment groups. Those who do not meet the inclusion criteria will receive routine HKC treatment and management.

All groups will receive treatment at both baseline and follow-up. At each treatment, Group 1 is the Rivastar 2-step group and children will receive 0.1 ml of Rivastar solution together with 0.1 ml step 2 (potassium iodide solution) . Group 2 will receive the Rivastar solution without the 'step 2'. Group 3 will receive the 'Rivastar version 2' solution (0.1 ml) and the 'step 2' solution (0.1 ml) at each treatment. Group 4 will receive the 'Rivastar version 2' solution only.

Updated 25/02/2019 to correct the doses:
All groups will receive treatment at both baseline and follow-up. At each treatment, Group 1 is the Rivastar 2-step group and children will receive 0.05 ml of Rivastar solution together with 0.1

ml step 2 (potassium iodide solution). Group 2 will receive the Rivastar solution without the 'step 2'. Group 3 will receive the 'Rivastar version 2' solution (0.05 ml) and the 'step 2' solution (0.1 ml) at each treatment. Group 4 will receive the 'Rivastar version 2' solution only.

Data will be collected at recruitment, during the baseline examination and at each AgF Application and data will include both a questionnaire as well as intraoral examinations. Each child will be assigned a unique identifier at baseline though the Healthy Kids Cambodia database system and that identifier will be used to track the child throughout the trial. Data analysis will be performed on a de-identified dataset only and in that way, the identity of participants will be protected.

Intervention Type
Mixed

Primary outcome measure
Stability of carious lesions defined based on (a) lesion progression (b) lesion colour and (c) lesion texture at 6 months and 12 months. Method for measurement of outcomes will be through clinical observation of the size of the carious lesion using the International Caries Detection and Assessment System version II (ICDAS-II) as well as observation of the color of the carious lesion and the hardness of the carious lesion.

Secondary outcome measures
The presence or absence of oral symptoms as defined by the presence or absence of an ‘impact’ on oral symptoms using the oral symptoms domain of the previously validated Child Perceptions Questionnaire at 6 months and 12 months

Overall study start date
01/10/2018

Completion date
31/03/2020

Eligibility

Key inclusion criteria
1. Children with one or more active carious lesions in primary tooth not involving the pulp
2. Participants who will begin the Healthy Kids Cambodia project in Takeo and Kampot provinces during the 2018-2019 academic year
3. Children in Grade 5 or below (age range 6-to 11 years of age)

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit

11 Years

Sex
Both

Target number of participants
353 carious lesions or up to 150 children per group

Total final enrolment
421

Key exclusion criteria
1. Children who are unable to provide adequate contact details/alternative contacts for reliable follow-up
2. Grade 6 and above children
3. Children belonging to families who have a plan to shift out of the region in the 12 months following recruitment
4. Children for whom their parents refuse consent at any stage during the study
5. Children who refuse assent at any stage during the study
6. Children with no teeth that are eligible to be included in the trial

Date of first enrolment
22/02/2019

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
Cambodia

Study participating centre
Faculty of Dentistry, University of Puthisastra
#55, street 180
Phnom Penh
Cambodia
12000

Sponsor information

Organisation
SDI Limited

Sponsor details

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3153

Sponsor type
Industry

Website
www.sdi.com.au

Funder(s)

Funder type
Industry

Funder Name
SDI Limited

Results and Publications

Publication and dissemination plan
6-month and 12-month results will be published

Intention to publish date
31/03/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Bathsheba Turton (bturton@puthisastra.edu.kh). Data will be available until 2025 for inclusion into meta-analysis. Consent for participants was obtained for use of data for research purposes only and de-identified data (only) could potentially be provided under reasonable request. The principal investigator retains full academic freedom for the use of the data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/07/2020	19/08/2020	Yes	No
Results article		28/12/2020	27/03/2023	Yes	No