ISRCTN16774328 https://doi.org/10.1186/ISRCTN16774328

Is it necessary to add chlorhexidine to a glass-ionomer restorative?

Submission date
28/12/2017

Recruitment status
No longer recruiting

Registration date
04/02/2018

Overall study status
Completed

Last Edited
29/01/2018

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
High-viscosity glass-ionomer (HVGIC) is a material that is used for tooth restorations (fillings). When preparing the tooth cavities, bacteria can be left behind, and some dentists think that new cavities can start. Other dentists disagree. Chlorhexidine (CHX) has antibacterial properties. Laboratory studies showed that HVGIC containing chlorhexidine (HVGIC/CHX) kills certain species of bacteria. The aim of this study is to find out whether HVGIC/CHX is more effective at preventing new cavities than HVGIC.

Who can participate?
Adolescents with at least two small/medium-sized cavities

What does the study involve?
Participants' cavities are randomly allocated to be restored with either HVGIC/CHX or HVGIC. The method is special as no drill is used in preparing the tooth cavity. Cavity preparation is done by hand instruments, which makes this method much more acceptable for the public and safer as less tooth tissue is removed compared to the drill method. Usually no anaesthetic is needed as pain is absent or very much reduced. The quality of the restoration and the presence of cavities are assessed after 0.5, 1, 1.5 and 2 years.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Dental School Cairo University (Egypt)

When is the study starting and how long is it expected to run for?
April 2007 to May 2009

Who is funding the study?
1. Cairo University (Egypt)
2. Radboud University Medical Center (Netherlands)
3. GC Europe (Belgium)

Who is the main contact?
Prof. Enas Mobarak

Contact information

Type(s)
Scientific

Contact name
Prof Enas Mobarak

Contact details
Faculty of Oral and Dental Medicine
Cairo University
Mailing address: 11 El Saraya st. Manial, Cairo, 12311
Cairo
Egypt
20177

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NRC280108

Study information

Scientific Title
Survival of occlusal ART restorations with and without chlorhexidine containing high-viscosity glass-ionomer: a 2-year split-mouth quadruple-blind randomized controlled clinical pilot trial

Study objectives
Would the use of HVGIC/CHX be more effective in preventing the occurrence of secondary carious lesions than HVGIC and would the survival of HVGIC/CHX restorations be higher than HVGIC restorations in occlusal cavities in permanent teeth treated according to ART?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethical committee at the National Research Center, Ministry of Health and Population, Government Health Insurance in Egypt, 14/10/2007, ref: NRC280108

Study design

24-month follow-up prospective randomized controlled split-mouth quadruple-blinded (operator, patients, evaluators and statistician) clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Dental cavitated teeth

Interventions
Considered a pilot study, a convenient sample size of 100 students per treatment group was chosen. Randomization of the two restoratives over the prepared cavities was performed as follows: 100 identical opaque sealed envelopes were prepared which included a number between 1 and 100. Each eligible student was asked to choose one envelop. The chosen number was taken as his/her identity code. If the number was an odd one, the molar at the right side was restored with material I and the molar at the left side with material II. If an even number was chosen, the molar at the right side was restored with material II and the left sided molar with material I.

Patients with at least two small-medium-sized occlusal cavities were included. Occlusal cavities were prepared according to the Atraumatic Restorative Treatment (ART) method and restored with either:
1. High-viscosity glass-ionomer with chlorhexidine (HVGIC/CHX) (test)
2. High-viscosity glass-ionomer (HVGIC) (control)

A replica of all restorations available and digital photographs were made at baseline and after 0.5, 1, 1.5 and 2 years, and evaluated by two examiners using the ART and FDI restoration assessment criteria. Estimation of survival curves was done with the Kaplan-Meier method. The logrank test was used to test for significance between the survival rates.

Intervention Type
Procedure/Surgery

Primary outcome measure
Development of secondary carious lesions, assessed using the USPHS criteria at baseline, 6, 12,18 and 24 months

Secondary outcome measures

Quality of the restorations, assessed using ART restoration criteria at baseline, 6, 12,18 and 24 months

Overall study start date
14/04/2007

Completion date
15/05/2009

Eligibility

Key inclusion criteria
1. Healthy patients without a history of any medical disease or condition that could interfere with the study protocol or affect clinical results
2. Patients without oral habits that could affect the study results
3. Presence of natural antagonist
4. Presence of at least two teeth with a cavitated dentine carious lesions in an occlusal surface in first or second permanent molars situated in different sides of the jaw
5. Occlusal cavities with size (Site/Stage 1.2 or 1.3)
6. Absence of apparent enamel crack or fracture
7. No pulp involvement or symptoms of pulpitis or apical periodontitis

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Poor oral hygiene
2. Deciduous teeth
3. Patients declaring daily consumption of substantial volume of citric juices

Date of first enrolment
15/01/2008

Date of final enrolment
14/02/2009

Locations

Countries of recruitment
Egypt

Study participating centre
Dental School Cairo University
Cairo
20711

Sponsor information

Organisation
Dental School University of Cairo

Sponsor details
11 El Saraya st. Manial
Cairo
Egypt
20177

Sponsor type
University/education

ROR
https://ror.org/03q21mh05

Funder(s)

Funder type
University/education

Funder Name
Cairo University

Alternative Name(s)
CU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Egypt

Funder Name
Radboud Universitair Medisch Centrum

Alternative Name(s)
Radboudumc, Radboud University Medical Center, Radboud University Nijmegen Medical Center, RUNMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Funder Name
GC Europe, Belgium

Results and Publications

Publication and dissemination plan
The manuscript has been submitted.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Radboud University Medical Centre.

IPD sharing plan summary
Available on request