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The effectiveness of fluoride varnish versus pit and fissure sealant for the prevention of caries in children of primary health care

Submission date 15/06/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/08/2009	**Overall study status** Completed	
Last Edited 18/08/2009	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Héctor Gatica Rossi

Contact details
Universidad de Chile
Independencia
Facultad de Medicina
1027 Módulo F. 3° Piso
Santiago
Chile
8380453

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SA08I20047

Study information

Scientific Title
Comparison of the effectiveness of fluoride varnish versus pit and fissure sealant for the prevention of caries in children of primary health care: randomised controlled clinical trial

Study objectives
The intervention of sealing pits and fissures of once a year application is more effective in reducing the incidence of caries when compared with application of fluoride varnish to 5% every six months, in children with an average age of 6 years for both sexes enrolled in schools in areas of low socioeconomic status and lower-middle of Santiago, Chile, considering clinically significant a reduction of 10% in the incidence of occlusal caries over a period of 12 months of follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Chile Faculty of Medicine Ethics Committee of Investigation in Humans Beings approved on the 8th August 2008 (ref: 065-2008)

Study design
Interventional prospective randomised single-blind controlled multicentre clinical trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Occlusal caries

Interventions
The choice of material to be used as a pit and fissure sealant in this project will be based on resin, since its use in primary care and is recommended by the Ministry of Health of Chile.

The sealant to be used in this study is the "Concise", manufacturer 3M, typically used in municipal health centers. The sealants should be given, taking into account the degree of eruption of first permanent molars, which is sufficient for proper application.

The procedure for applying a resin-based sealants must be sequenced according to the rules and recommendations established by the manufacturer. The staff that will be used to implement the experimental maneuver consists of dentists of Primary Health Care, which will be previously trained regarding the application of interventions. If during the execution of the study, a primary care dentist eventually shows little interest or fails to fulfill its tasks, he (or she) will be replaced by a dentist or a student of final year of odontology, previously trained.

The other intervention to be applied is the sodium fluoride varnish 5% (22,600 ppm. fluoride). This branch will be considered the control group. This material is indicated for the prevention of caries in occlusal surfaces of molars and pre molars and in smooth surfaces, and its application is recommended in all patients with moderate and high caries activity or cariogenic risk. The varnish used in this study is called "Duraphat to 5%", of the manufacturer Colgate.

The application is performed according to manufacturer's instructions. Human resources involved in the application of fluoride varnish is the same as the application of sealants. In this work, the varnish is applied, initially at the start of the investigation, and every 6 months, according to the recommendations established by national experts, until the end of the monitoring period, we will seek caries lesions in early stages of the process.

Due to the complexity of clinical trials, and the time at which the outcome is measured, it requires at least 24 months to implement the study. Students in this study will be followed by at least 1 year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Early stages of the process of occlusal caries in molars, prior to the formation of cavity with obvious dentine exposure, made on the basis of the criteria proposed by the International Caries Detection and Assessment System Coordinating Committee (ICDAS II).

All outcomes measured in July 2010.

Secondary outcome measures
1. Proportion of loss for the pit and fissure sealants in a period of 1 year follow up
2. Partial and total loss of pit and fissure sealants on the occlusal surface of permanent first molars, through visual examination

All outcomes measured in July 2010.

Overall study start date
01/05/2009

Completion date
01/05/2011

Eligibility

Key inclusion criteria
1. Children of both sexes, 6 years old on average (or already in the process of eruption of first permanent molars)
2. Socio-economic levels belonging to medium-low or low status
3. Presenting at least one of the first permanent molars compatible with the application of materials, and free of clinically detectable caries (with exposed dentine) or fillings at the time of the beginning of the study
4. Who are willing to participate in the study, confirmed that by signing the informed consent letter for parents

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
193 students per group; total of 386 children

Key exclusion criteria
Children that need some kind of special attention, as a procedure under general anaesthesia, presence of systemic disease or neurological limitations that impede their attention by a general dentist.

Date of first enrolment
01/05/2009

Date of final enrolment
01/05/2011

Locations

Countries of recruitment
Chile

Study participating centre
Universidad de Chile
Santiago
Chile
8380453

Sponsor information

Organisation
Universidad de Chile (Chile)

Sponsor details
c/o Dr. Héctor Gatica Rossi
Independencia
Facultad de Medicina
1027 Módulo F. 3º Piso
Santiago
Chile
8380453

Sponsor type
University/education

Website
http://www.uchile.cl/

ROR
https://ror.org/02xtpdq88

Funder(s)

Funder type
Government

Funder Name
National Commission for Science and Technology, Government of Chile (CONICYT) (Chile) - National Fund for Research and Development in Health (FONIS) (ref: SA08I20047)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration