Plan Overview

A Data Management Plan created using DMPTool-Stage

Title: Impact of the radiographic examination on diagnosis and treatment decision of caries lesions in primary teeth - the Caries Detection in Children (CARDEC-01) trial

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Funder: São Paulo Research Foundation (fapesp.br)

Grant: 2012/24243-7

Template: USP Template - Minimum

Project abstract:

Background: Although most clinical guidelines throughout the world indicate that clinicians take two bitewings for detecting caries lesions in primary molars of all children, evidence for this recommendation is essentially based on cross-sectional studies performed at laboratorial setting or using convenience samples. Benefits and impact of performing radiographs on diagnosis and treatment decision of caries lesions in primary teeth, mainly considering relevant outcomes for patients, have not been evaluated yet. Thus, the aim of this randomized clinical trial will be to evaluate the impact of performing radiographic examination adjunct to the visual inspection for detecting and making treatment decision regarding caries lesions in primary teeth compared with visual inspection performed alone. We will consider different outcomes related to children's health and welfare. Methods: To reach this objective, 250 children aged 3 to 6 years who looked for dental treatment in our dental school will be randomly allocated in two groups according to diagnostic strategy used for caries detection: visual inspection performed alone or visual inspection associated to radiographic examination. Two trained and calibrated examiners will carry out the examinations and elaborate the treatment decision plan. Then, children will be treated and followed-up for 2 years, with evaluations after 12 and 24 months after the inclusion of children in the study. Children will also return after 6 and 18 months for reinforce the preventive orientations. Primary outcome will be the number of dental surfaces with dental treatment need in follow-up. Secondary outcomes will be the components of the primary outcome separately, as well as, proportion of false-positive results, the oral health-related quality of life, cost-efficacy, cost-adjusted per life years and number of new lesions in the first permanent molars. Discussion: Our working hypothesis is that radiographic examination would actually exert little influence on patient-centered outcomes, and that visual inspection would be enough as

diagnostic strategy for caries detection in primary teeth. Trial registration: www.clinicaltrials.gov, NCT02078453. Registered 4 March 2015

Start date: 03-23-2013

End date: 12-30-2020

Last modified: 10-03-2020

Copyright information:

Impact of the radiographic examination on diagnosis and treatment decision of caries lesions in primary teeth - the Caries Detection in Children (CARDEC-01) trial - Description of Data and Metadata produced by the project

We collected data of preschool children related to procedures of caries diagnosis and subsequent treatment in their primay molars. Data is related to the examination and dental treatment conducted at the baseline, and the occurrence of new interventions during the follow-up. Data is codified in numbers with the respective subtitles in an excel worksheet.

Data will be collected through validated index systems, and data will be added to a excel worksheet.