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Testing two ways to diagnose tooth decay that will affect the way that dentists decide on treatment

Submission date
19/10/2012

Recruitment status
No longer recruiting

Registration date
07/11/2012

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Caries (also known as tooth decay or cavities are usually diagnosed on its cavitated stage and treated by drilling tooth tissue and applying a restorative material (like a filling). However, the restorations have their own life span and can be broken or lost with time. This will lead to re-restoration procedures, with subsequent tooth tissue loss. It is well known that the caries process includes several stages, from non-cavitated (early) to cavitated, and both stages can be active and inactive. Active caries should be treated, while in-active stages should not. Moreover, active non-cavitated caries can be treated and stopped using non-operative treatment. Therefore, using appropriate diagnostic criteria that can detect caries from their early stage, as well as assess their activity, is very important. Recently, two promising visual/visual-tactile caries diagnostic systems, the Nyvad and the ICDAS II were introduced. They have shown to be reliable and accurate and were used in several surveys and studies. However, since both systems have the potential to be used in clinical practice, it is important to investigate their implications on caries treatment decisions amongst dentists. The aim of this study is to compare the two different methods to how well they are used in caries treatment decision making in dentists.

Who can participate?
Dentists who are not aware about ICDAS II or Nyvad diagnostic systems and paitents aged 18 to 20 who have cavities

What does the study involve?
For the all dentists, a lecture concerning contemporary caries management strategies was given. Dentists are randomly assigned to one of two groups. Those in the first group use the Nyvad criteria in their first period and are followed up the ICDAS II criteria during the second period. Those in the second group use ICDAS II criteria during the first period and use the Nyvad criteria during the second period. Before the first period of examinations, dentists from the first group were trained with the Nyvad criteria, while dentists belonging to the second group were trained with the ICDAS II criteria. During the washout period, both groups of dentists were trained again:

the first group with the ICDAS II criteria and the second group with the Nyvad criteria. After each examination, dentists were asked to make treatment decisions for each surface of the patients' teeth.

What are the possible benefits and risks of participating?
Participating patients may benefit from receiving detailed information concerning their teeth and their oral health. They may benefit from receiving toothbrushes and fluoridated tooth pastes. Participating dentists may benefit from new knowledge in detecting and treating cavities. There are no notable risks with participating, however patients may experience some discomfort in their jaw during the dental examinations. Dentists may experience discomfort from repeated dental examiniations.

Where is the study run from?
This study is being run by McGill University and takes places in a dental unit of the Institute of Emergency Services of Belarus (Minsk, Belarus).

When is the study starting and how long is it expected to run for?
November 2010 to December 2010

Who is funding the study?
McGill University (Canada)

Who is the main contact?
Svetlana Tikhonova
svetlana.tikhonova@mail.mcgill.ca

Contact information

Type(s)
Scientific

Contact name
Dr Svetlana Tikhonova

Contact details
McGill University
4-3803 St-Hubert Str.
Montreal
Canada
H2L4A4
15142657624
svetlana.tikhonova@mail.mcgill.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A12-E60-10A

Study information

Scientific Title
A comparison of treatment choices when dental caries lesions are diagnosed with two visual-tactile systems the Nyvad and the ICDAS II

Study objectives
1. A mean number of operative treatments estimated by dentists with the Nyvad system will be at least one unit less in comparison with the International Caries Detection and Assessment System (ICDAS) II system.
2. A mean number of non-operative treatments estimated by dentists with the Nyvad system will be at least three units less in comparison with the ICDAS II system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of McGill University, Montreal, Canada ref: A12-E60-10A, 2010
Research Ethics Committee of Belarusian State Medical University, 06 October 2010

Study design
Cross-over two-period (AB/BA) single blind clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
https://docs.google.com/open?id=0B4EyAvWIgprPWUQzMFJBZm9Bd3c

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

Interventions
The dentists were randomly assigned to one of two groups; each group had two dentists. Both groups of dentists examined the same patients (n=140) using the Nyvad and the ICDAS II criteria in different sequences. The first group used the Nyvad criteria during period 1, followed by ICDAS II criteria during period 2; the second group used the ICDAS II criteria during period 1, followed by Nyvad criteria during period 2. It was a one week washout period between period 1

and period 2 examinations. Before the first period of examinations, dentists from the first group were trained with the Nyvad criteria, while dentists belonging to the second group were trained with the ICDAS II criteria. During the washout period, both groups of dentists were trained again: the first group with the ICDAS II criteria and the second group with the Nyvad criteria. After each examination, dentists were asked to make treatment decisions for each surface of the patients teeth.

Deatils of co-sponsor:
Belarussian State Medical University
83, Dzerzinski Ave.
Minsk, Belarus 220116
Tel. +375 17 272 66 05

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Number of surfaces per individual requiring operative or non-operative treatment measured at the same time twice: in period 1 of examination and in a one week in period 2 of examination

Secondary outcome measures
Diagnostic outcomes:
1. Nyvad D and ICDAS II D components reflecting activity of the lesions (active non-cavitated lesions, active cavitated lesions, inactive non-cavitated lesions, inactive cavitated lesions).
2. Nyvad D and ICDAS II D (decay) components reflecting activity and depth of the lesions
3. Caries experience of carious lesions (mean DMFS) generated from the Nyvad and the ICDAS II systems

Overall study start date
03/11/2010

Completion date
05/12/2010

Eligibility

Key inclusion criteria
Dentists:
1. Dentists preliminary not aware about ICDAS II or Nyvad diagnostic systems
2. Five to ten years of clinical experience
3. The same university of graduation
4. Same specialization (operative dentistry)
5. Same clinical environment
6. Working with the same adult population (with similar caries prevalence and experience)

Patients:
1. Age of 18-20 years old
2. Males and females
3. Patients having ≥2 active non-cavitated and/or cavitated carious lesions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
20 Years

Sex
Both

Target number of participants
140

Total final enrolment
140

Key exclusion criteria
Patients:
1. Caries inactive group (no or maximally one active lesion)
2. Patients with fixed orthodontic devices
3. Patients with severe fluorosis or hypoplasia
4. Patients with complicated chronic diseases that can produce modifications in treatment choosing

Date of first enrolment
03/11/2010

Date of final enrolment
05/12/2010

Locations

Countries of recruitment
Belarus

Canada

Study participating centre

McGill University
Montreal
Canada
H2L4A4

Sponsor information

Organisation
McGill University (Canada)

Sponsor details
Faculty of Medicine
3655 Promenade Sir William Osler
Montreal, QC
Canada
H3G1Y6

Sponsor type
University/education

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
University/education

Funder Name
McGill University (Canada)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2014	17/12/2020	Yes	No