

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

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<b>Registration date</b> 07/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/12/2020	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English Summary

### 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 patients aged 18 to 20 who have cavities

### What does the study involve?

For 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 examinations.

Where is the study run from?

This study is being run by McGill University and takes place 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 hypothesis

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=0B4EyAvWlIgprPWUQzMFJBZm9Bd3c>

## Condition

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.

Details 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

### **Overall study end date**

05/12/2010

## **Eligibility**

### **Participant 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  $\geq 2$  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

**Participant 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

**Recruitment start date**

03/11/2010

**Recruitment end date**

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?
<a href="#">Results article</a>	results	01/11/2014	17/12/2020	Yes	No