

# Diagnostic image quality in intra-oral radiography, comparison of hand held and wall mounted X-ray devices; A non-inferiority study with the Nomad Pro hand held X-ray device.

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To test if diagnostic quality of radiography with portable devices is non-inferior to that of radiography with wall mounted devices.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON48165

### Source

ToetsingOnline

### Brief title

Diagnostic quality of hand held intra-oral radiography

### Condition

- Other condition

### Synonym

cavities in teeth, tooth decay

### Health condition

gebitaandoeningen: cariës: parodontale aandoeningen

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Centrum Tandheelkunde Amsterdam ACTA

**Source(s) of monetary or material Support:** Ministerie van OC&W,bedrijf,Kavo Kerr Group

## Intervention

**Keyword:** dental equipment, dental radiography, diagnostic equipment, diagnostic imaging

## Outcome measures

### Primary outcome

Preference for HH, for WM or no preference for the diagnostic image quality rated by 3 observers. The majority of the three observers determines the verdict, if no majority is present (all scored differently) the score no preference will be given.

### Secondary outcome

- \* Inter-examiner reliability
- \* Differences between left and right sided exposure, and between first and second exposure
- \* Dependency of the rating of images within the patients

## Study description

### Background summary

Hand held X-ray devices (HH) potentially provide advantages for dental intra-oral radiography over fixed wall mounted devices (WM). They can be used when visiting non-mobile patients or in part time dental clinics in remote, sparsely populated areas in developing countries. Moreover, in the dental office, one HH device can serve multiple suites instead of one WM device for

each suite. This limits financial investments in devices and cabling. This potentially improves the accessibility of dental care. Recent studies have proved that with judicious use, Conformité Européenne (CE) approved devices such as the Nomad Pro, do not pose a threat for the operator or patient. An issue that has not been clarified in an adequate clinical study is whether the diagnostic image quality of HH devices is not inferior to WM devices.

## **Study objective**

To test if diagnostic quality of radiography with portable devices is non-inferior to that of radiography with wall mounted devices.

## **Study design**

We compare the 2 diagnostic modalities in a clinical experimental non inferiority study. Bitewing (BW) exposures are made twice, once with HH and once with WM in random order without changing any other factor. Blinded observers rate the pairs of images displayed side by side for their preference regarding diagnostic quality. Three outcomes are possible: preference for WM, for HH or no preference. The hypothesis of non-inferiority will be rejected by a difference found larger than 10% ( $p < .05$ )

## **Intervention**

performing extra bitewing exposures, one on right side and one on the left side

## **Study burden and risks**

The inconvenience for the patient exists in the fact that the sensor holder has to stay in the mouth longer to facilitate the second exposure with the other modality. This will be less than a minute.

The extra dosage that is administered is the dose needed to perform the extra exposures. The dose and risk of these exposures is trivial being 0.4  $\mu\text{Sv}$  per BW exposure. The extra dose a participant of this study receives is 0.8  $\mu\text{Sv}$ . The individual risk for the participant of a lethal stochastic event from this dose would be 1 in 25 million.(ICRP 2007)

There are no direct benefits for the health of the participant, the yield lies in advancing knowledge about dental radiography which could in the long run indirectly benefit the participant.

The group relatedness is excellent as portable X-ray devices will be deployed for the targeted patients in daily general dental practice.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

justification for bitewing radiography

age 18 or older

legally competent

dentate

willing to cooperate

signing consent form

### Exclusion criteria

- The patient is not able to cooperate during the BW procedure.
- The patient has no post-canine teeth to be depicted on the BW in upper and or

lower jaw.

- The patient is or might be pregnant

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 08-10-2019

Enrollment: 205

Type: Actual

### Medical products/devices used

Generic name: Hand held X-ray device Nomad Pro 2

Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 19-07-2019

Application type: First submission

Review commission: METC Amsterdam UMC

## Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

ID: 24818

Source: NTR

Title:

## In other registers

Register	ID
CCMO	NL69402.029.19
OMON	NL-OMON24818

## Study results