

Survival and success of endodontically treated teeth with a minimum service time of 12 months: a prospective cohort study.

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to assess the endodontic and restorative survival of teeth after root canal treatment and the endodontic and restorative success of the root canal treatment performed at the Special Dental Care Center of the Martini Hospital.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON46027

Source

ToetsingOnline

Brief title

Survival and success of endodontically treated teeth

Condition

- Other condition

Synonym

Peri-apical periodontitis

Health condition

tandheelkundig

Research involving

Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Endodontic, Healing, Restorative, Root canal treatment

Outcome measures

Primary outcome

Kaplan-Meier success (root canal therapy; event: non-healed cases) and survival (tooth level; event: extraction) rates

Secondary outcome

Secondary outcome measure is the healing after root canal treatment (success).

Healing is divided into two categories:

* Strict criteria

1. Absence of clinical symptoms;
2. Absence of a peri-apical radiolucency on the radiograph.

* Less strict criteria

1. Absence of clinical symptoms;
2. Absence or reduction of a peri-apical radiolucency on the radiograph.

Clinical performance of the restorations (USPH / Hickel)

Study description

Background summary

Rationale: to assess the endodontic and restorative survival of teeth after root canal treatment and the endodontic and restorative success of the root canal treatment performed at the Special Dental Care Center of the Martini Hospital.

Objective: to evaluate tooth survival, root canal therapy success and the quality of the restoration.

Study design: a prospective cohort study.

Study population: patients who received root canal therapy at the Special Dental Care Center of the Martini hospital, who are over 18 years of age and mentally competent. The root canal therapy should have clinical service time of at least 12 months.

Intervention (if applicable): no intervention is carried out.

Main study parameters/endpoints: Kaplan-Meier survival (tooth level) and success (root canal therapy) rates.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: No additional risks are anticipated, since this is a non-invasive study. Participants will be asked to attend to an evaluation appointment to assess clinically the absence of symptoms after root canal therapy, as is standard care.

Study objective

to assess the endodontic and restorative survival of teeth after root canal treatment and the endodontic and restorative success of the root canal treatment performed at the Special Dental Care Center of the Martini Hospital.

Study design

Prospective cohort study

Study burden and risks

None

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

Patients who received a root canal treatment at the Martini hospital

Clinical service time of at least 12 months

Healthy subjects and mentally competent * 18 years of age

Exclusion criteria

Root canal treatment with a clinical service time < 12 months

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 02-02-2019
Enrollment: 430
Type: Actual

Ethics review

Approved WMO
Date: 03-12-2018
Application type: First submission
Review commission: RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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: 28434
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65516.099.18
OMON	NL-OMON28434