Clinical evaluation of posterior glass-ceramic partial restorations luted in conjunction with Immediate Dentin Sealing

Gepubliceerd: 28-10-2020 Laatst bijgewerkt: 18-08-2022

Overall survival rates after 7-9 years of evaluation will be over 90%.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27451

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Caries, periodontal disease, pulpal disease, fracture

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Centre Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Indirect restorations with IDS at preparation are likely to survive on the long-term.

Toelichting onderzoek

Achtergrond van het onderzoek

Large sized cavities can be restored using partial indirect ceramic restorations since these restorations can properly restore the morphology and function of the tooth. However, lithium disilicate restorations are prone to bulk fracture, chipping and adhesive problems. Adhesive problems are combatted by the use of Immediate Dentin Sealing (IDS). IDS has proven to significantly increase the fracture strength of lithium disilicate restorations.
Not many long term clinical knowledge is present on the survival and performance of these restorations in combination with IDS. Therefore, this clinical trial investigates the survival rate of partial indirect lithium disilicate restorations in conjunction with IDS.
Approximately 2000-3000 restorations will be included in the study. The primary outcome will be the survival of the lithium disilicate restorations. Data will be collected from digital light photo’s, X-rays and patient files. These are part of regular dental care and therefore no extra burden for the patient. This study will be registered as a non-objection study. Data will be analyzed using a Kaplan-Meier survival analysis with Log rank tests and Cox regression multi-level analysis with paired data (with frailty model). Overall survival rates after 7-9 years of evaluation are expected to be over 90%. Moreover, this study might be able to identify the influence of risk factors and patient factors on survival.

Doel van het onderzoek

Overall survival rates after 7-9 years of evaluation will be over 90%.

Onderzoeksopzet

Initial at baseline, at every check up (every 6 months), up to 15 years of follow-up

Onderzoeksproduct en/of interventie

Indirect restoration of ceramic material with application of Immediate Dentin Sealing at preparation.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients who received indirect partial lithium disilicate restoration from 2008 are eligible for inclusion. Patients have to be at least 18 years of age and have to be physically and psychologically able to tolerate restorative procedures. IDS must be applied at every preparation. Moreover, the candidate is a patient at Buijs Tandartsen.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Not willing to enroll in the study, changing dentist or having moved to another city or dental practice after restoration.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	3000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
All patients agreed on participation by a register of non-objection. This research is approved by the METc Groningen as non-WMO, since no extra burden will be brought to the patient.

Ethische beoordeling

Positief advies

Datum:	28-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9026
Ander register	METC UMCG : METC202000588

Resultaten

Samenvatting resultaten
This retrospective database is aimed to be published in a Q1 journal.