The tolerance to RISA root canal irrigation fluid determined in an in-vivo study

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To assess the tolerance of RISA after its application in the root canal system during root canal treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45736

Source
ToetsingOnline

Brief title
TIGRIS

Condition

- Other condition
- Ancillary infectious topics

Synonym
apical periodontitis, root tip inflammation

Health condition

lokale ontstekingsreactie als gevolg van een lokale afgebakende infectie in een gebitselement

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Centrum Tandheelkunde Amsterdam (ACTA)
Source(s) of monetary or material Support: ACTA Dental Research B.V.

Intervention

Keyword: endodontic, irrigation, postoperative, root canal treatment

Outcome measures

Primary outcome

Frequency and intensity of postoperative pain. Quantity of pain medication

taken before and after the root canal treatment.

Secondary outcome

Periapical lesion size before root canal treatment and one year after root

canal treatment.

Study description

Background summary

The prevalence of root tip inflammation after root canal treatment is very high (45%). A very important reason is that the root canal infection can (partly) persist after root canal treatment. Current root-canal irrigation fluids are surface disinfectants and they are not able reach the complexity of root canal systems. Moreover, currently most used root canal irrigation fluid is a sodium hypochlorite solution which is a highly corrosive solution. After a series of laboratory tests, where RISA root-canal cleanser (RISA) showed good cleaning and biocompatible properties, the tolerance of the newly-devised compound is to be tested in the clinic in humans.

Study objective

To assess the tolerance of RISA after its application in the root canal system during root canal treatment.

Study design

Prospective case-series

Intervention

Teeth are treated with a non-surgical root canal treatment (NSRCT with RISA irrigation. During a NSRCT RISA is going to be used instead of the currently employed 2%-sodium hypochlorite solution, to lubricate the root canal instruments and the rinse the debris from the root canals.

Study burden and risks

The burden associated with participation consists of filling out one questionnaire pre-operatively and seven questionnaires postoperatively. The questionnaires contain a maximum of four questions. The risk associated with participation is negligibly small. There will be no direct benefit for the subjects as the applicability of RISA is to be established in this clinical case series.

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

- apical periodontitis has been diagnosed and confirmed with an intra-oral radiograph and appears on the radiograph as a radiolucent area around one or more root tips of the affected tooth. A root canal treatment has a reasonable/good prognosis (Sjögren et al. 1990) and the subject prefers NSRCT over tooth extraction or monitoring. The affected tooth has not previously received a complete root canal treatment.
- no spontaneous pre-operative pain or spontaneous pre-operative pain less than 36
- no or mild swelling
- if present, draining or no-draining sinus tract
- 18 - 75 years.
- completed the medical history questionnaire.
- all teeth except third molars
- DPSI of subject tooth is <=3-
- tooth mobility <=1
- signed the informed consent form

Exclusion criteria

Subject tooth related criteria:
- third molar
- pain >36 on Heft-Parker VAS scale (fig. 1)
- subject tooth with a mobility score 2 or more
- subject tooth with a periodontal pocket depth DPSI >=3+
- subject tooth with open or incompletely formed root apices
- subject tooth that requires a post
- subject tooth with a vertical fracture or horizontal fracture extending below the cemento-enamel junction of the tooth
- teeth in the same quadrant requiring root canal therapy
- teeth with hypersensitive dentine in the same left or right facial half
- absence of periapical radiolucency in the presence of tenderness to percussion.
- absence of periapical radiolucency in the absence of pulp sensitivity
- previous completed (non)surgical (root-canal) treatment on subject tooth
- severe swelling originating from affected tooth;Current medication related criteria:
- chronic use of pain relief medication
- (par)enteral use of bisphosphonates
- systemic corticoid therapy;General-health related criteria:
- non-odontogenic facial pain

- any known infectious diseases (eg, human immunodeficiency virus, hepatitis B, hepatitis C, tuberculosis, or prion induced disease)
- history of cancer in the oral-maxillofacial region
- history of cancer in the last two years
- history of head and/or neck radiation therapy
- diabetes mellitus type I,
- chronic inflammatory diseases like morbus Crohn or rheumatoid arthritis

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	05-10-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-02-2018
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL59783.029.17

Study results

Date completed:	29-06-2021
Actual enrolment:	18