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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25853

Source
NTR

Brief title
TIGRIS (Tolerance IrriGation RISa)

Health condition

Apical periodontitis, pain

Sponsors and support

Primary sponsor: ACTA Dental Research B.V.
Source(s) of monetary or material Support: Coltène / Whaledent GmbH + Co. KG

Intervention

Outcome measures

Primary outcome

pain / no pain

Secondary outcome

healing apical periodontitis

Study description

Background summary

Rationale: After a series of laboratory tests, where RISA root-canal cleanser (RISA) showed good antimicrobial and biocompatible properties, the tolerance to the newly-devised compound is to be tested in the clinic in humans.

Primary objective: To assess the tolerance to RISA after its the application in the root-canal system during root canal treatment.

The secondary objective is to evaluate periapical radiolucency size on intra-oral radiographs of teeth treated with RISA.

Study objective

Well-being after root canal treatment with RISA irrigation. Frequency and intensity of postoperative pain.

Study design

intake, consultation, treatment, control after 1 year a total of 7 questionaires are filled out

Intervention

irrigation RISA

Contacts

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Eligibility criteria

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 (see fig. 1) (Heft & Parker 1984)

- no or mild swelling and no draining sinus tract on affected tooth.

- 18 – 75 years.

- completed the medical history questionnaire.

- 1st or 2nd molar, 1st or 2nd premolar

- DPSI of subject tooth is ≤3-

- tooth mobility ≤1

- signed the informed consent form

Exclusion criteria

- pain >36 on Heft-Parker VAS scale (fig. 1)

- subject tooth with a mobility score 2 or more

- subject tooth with a 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 a periapical

- previous (non)surgical (root-canal) treatment on subject tooth

- draining sinus tract or exacerbation 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/II,

- chronic inflammatory diseases like morbus Crohn or rheumatoid arthritis

- known sensitization to sorbic acid and its salts

- pain >36 on Heft-Parker VAS scale (fig. 1)

- subject tooth with a mobility score 2 or more

- subject tooth with a DPSI ≥3+

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- subject tooth that requires a post

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Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2017
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-10-2017
Application type:	First submission

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
NTR-new	NL6588
NTR-old	NTR6762
Other	: 2017.015

Study results

Summary results

1: van der Waal SV, Scheres N, de Soet JJ, Wesselink PR, Crielaard W. Cytotoxicity, interaction with dentine and efficacy on multispecies biofilms of a modified salt solution intended for endodontic disinfection in a new in vitro biofilm model. Int Endod J. 2015; 48:153-61.

2: van der Waal SV, Jiang LM, de Soet JJ, van der Sluis LW, Wesselink PR, Crielaard W. Sodium chloride and potassium sorbate: a synergistic combination against Enterococcus faecalis biofilms: an in vitro study. Eur J Oral Sci. 2012