

Clinical and microbiological evaluation of pocketirrigation in generalized advanced periodontitis

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

Summary

ID

NL-OMON34874

Source

ToetsingOnline

Brief title

pocketirrigation and periodontitis

Condition

- Other condition

Synonym

periodontitis or gum diseases

Health condition

tandvleesaandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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

Intervention

Keyword: advanced periodontitis, pocketirrigation, scaling and rootplaning

Outcome measures

Primary outcome

pocketdepth at 6 sites around the teeth measured with a calibrated pocket probe

qualitative microbiological scores

These parameters are recorded before and 3 months after treatment

Secondary outcome

The following other parameters are assessed at the same timepoints also at the

6 sites around the teeth:

- plaque score
- gingival score
- gingival recession towards the cemento-enamel junction in mm
- CAL: clinical attachment level, counted from the pocketdepth and the recession

Study description

Background summary

Pocketirrigation has been done since many decades with very limited effect (

Greenstein, positionpaper, AAP, 2005). Even when subgingival irrigation was performed in conjunction with scaling and rootplaning (SRP) the adjunctive effect of irrigation with or without medicaments was controversial.

The conclusion of the position paper was that there is no evidence that subgingival irrigation routinely should be used as a supplemental procedure to augment the effect of SRP.

A new apparatus was designed to irrigate pockets using a small underpressure enabling the irrigationfluid to reach the depths of the pocket. The apparatus, called the Pocketirrigator, consists of a base-station and a handpiece.

Laboratory studies of the Pocketirrigator show fluidcirculations, kind of whirls, which reach the complete area to irrigate. When fluid is brought in with a needle, imitating the available tools, only the vicinity of the needle is irrigated.

In a pilotstudy 6 patients with advanced periodontitis were treated with the irrigation device on one side where the other side was treated with SRP.

Results of both treatment modalities were similar. A great reduction in plaque, bleedingtendency and pocketdepth was obtained. Pocketdepth of 7 mm and more were reduced with 3.5 mm in both the irrigation as well as in the SRP side.

Study objective

The aim of the study is to test the effectiveness of the Pocketirrigator in patients with generalized advanced periodontitis and to compare this with traditional scaling and rootplaning (SRP).

Research questions are:

- 1) is the clinical outcome of irrigation as good as SRP
- 2) is 6 times irrigation, twice weekly for 3 weeks sufficient for getting a clinical relevant result
- 3) is the microbiological outcome after irrigation different from SRP
- 4) does irrigation selectively influence the subgingival microflora

Study design

Clinical and microbiological investigation by a periodontist

Initial periodontal treatment by a dental hygienist in 3 consecutive weeks

Clinical and microbiological evaluation after 3 months by the same periodontist

The initial treatment consists of:

- oral hygiene instructions
- supragingival cleaning
- subgingival cleaning by instruments or
- subgingival cleaning with the Pocketirrigator on the contralateral side
- a 2nd irrigation on the irrigation side in the same week

It is decided by flip of the coin by the dental hygienist which side is irrigated with the Periosonic.

Periodontists/ examiners do not know which side is irrigated.

Supragingival cleaning is done 4 weeks before the evaluation in order to make it impossible for the examiner to see which side is irrigated.

Microbiological samples are taken before treatment, in the third week of treatment, just after the subgingival cleaning and 4 weeks before the evaluation.

Intervention

Patients with a advanced periodontitis, who are selected for this study are treated on a normal standardized way.

The first phase of the treatment consists of oral hygiene instructions and supra- and subgingival cleaning.

In this study it is tested whether the subgingival cleaning which normally is done with curettes can be replaced by pocketirrigation.

Study burden and risks

Treatment as done in this study is the standard treatment for periodontal diseases, except for the irrigation which is done on one side of the jaw. Irrigation is done with the Pocketirrigator, is not invasive and takes place under a very small negative pressure. Irrigation is done with water, is painless and not unpleasant in contrast with the standard cleaning with SRP which needs often local anaesthesia.

Since irrigation is not invasive it is believed that bacteriemia which takes place with SRP will not occur.

Irrigation is done twice weekly for 3 weeks, whereas the SRP needs only one session per week. On the other side, one pocketirrigation takes only 5-10 minutes for a whole mouth whereas SRP needs more than 2 hours.

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 with generalized advanced periodontitis

Exclusion criteria

no systemdisorders; pregnant;no antibioticum use since 3 months;no partial dentures;no previous periodontal treatment

Study design

Design

Study type: Interventional

Masking:

Single blinded (masking used)

Control:

Uncontrolled

Primary purpose:

Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO	
Date:	05-11-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL31743.042.10