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Formulation and evaluation of new biodegradable periodontal chip containing Selvadora Persica in chitosan base for the management of chronic periodontitis

Submission date
02/12/2012

Recruitment status
No longer recruiting

Registration date
26/02/2013

Overall study status
Completed

Last Edited
16/10/2017

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Periodontitis is a severe form of gum disease. If periodontitis isn't treated, small pockets can open up between the gum and teeth, providing a space for bacteria to live. PerioChip® is a biodegradable chip for reducing pocket depth in periodontitis when used alongside scaling and root planing. The branches of the Salvadora persica tree have been used for centuries as a natural toothbrush. They contain benzylisothiocyanate (BITC), which has an antibacterial action. The aim of this study is to develop a biodegradable chip containing Salvadora persica and to test its effectiveness at treating periodontitis.

Who can participate?
Men aged between 35 and 56 with periodontitis

What does the study involve?
The participants' periodontal pockets are randomly allocated into one of four groups. Group 1 are treated with scaling and root planing alone (control group). Group 2 are treated with scaling and root planing followed by Chitosan chip insertion. Group 3 are treated with scaling and root planing followed by Salvadora persica chip insertion. Group 4 are treated with scaling and root planing followed by insertion of a chip containing BITC. Patients are examined 2 days after the placement of chips. Patients are instructed not to use dental floss for 10 days to avoid displacement of the chip, or any type of mouth rinses or oral irrigation device during the study period. At day 14 patients are recalled for a second chip insertion. Plaque, bleeding on probing and pocket depth are measured on day 0 and day 60 after treatment.

What are the possible benefits and risks of participating?
The possible benefits are to treat periodontitis with a non-surgical procedure by providing scaling and root planing for each patient. There are no risks of participating in this study unless the patient is allergic to Salvadora persica.

Where is the study run from?
Universiti Teknologi MARA (Malaysia)

When is the study starting and how long is it expected to run for?
April 2011 to December 2011

Who is funding the study?
Universiti Teknologi MARA (Malaysia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5/1/6/01

Study information

Scientific Title
Formulation and evaluation of new biodegradable periodontal chip containing Selvadora Persica in chitosan base for the management of chronic periodontitis: a randomized single-blind split mouth study

Study objectives
Therapeutic uses of Salvadora Persica have been found in toothpaste, mouth rinses and endodontic irrigation solution. This newly formulated periodontal chips containing Salvadora persica can be utilized as adjuncts to scaling and root planning in the managements of chronic periodontitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Management institute, Universiti Teknologi MARA, 20/04/2011, ref: 600-RMI(5/1/6/01)

Study design
Two month randomized single-blind split mouth study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic periodontitis

Interventions
At baseline, all patients were treated with full mouth scaling and root planning. Periodontal pockets were divided into four groups. One of which is the control group, while group two received plain Chitosan chip. Group three received chips containing Salvadora persica extract and group four received chips containing Benzylisothiocyanate.

Plaque index, bleeding on probing, periodontal probing pocket depth and clinical attachment levels using acrylic stents were recorded at day 0 and 60.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Current primary outcome measures as of 03/05/2013:
In the current study the gel diffusion, Minimum Inhibitory Concentration (MIC) Minimum Bactericidal Concentration (MBC) tests and assessment of Bacteria Morphology with Scanning Electron Microscope (SEM) were used to evaluate the antibacterial effect of Salvadora persica extract and BITC chips on dental biofilm bacteria, results showed that both were able to inhibit bacteria growth and produced obvious alterations to the bacterial morphology.
The result showed reductions in Probing Pocket Depth (PPD) in all 4 groups and these reductions are statistically significant in all 4 groups (p=0.01). The effects of the treatments were evident post treatment recording. At 2 months, PPD was reduced to 4.52 mm in the SRP alone group, to 5.27 in SRP plus chitosan, to 5.60 mm in the SRP plus Salvadora Persica chip group and to 4.63 mm in the SRP plus BITC chip group contrasted with pre-treatment records.

Previous primary outcome measures until 03/05/2013:
The result showed reductions in Probing Pocket Depth (PPD) in all 4 groups and these reductions are statistically significant in all 4 groups (p=0.01). The effects of the treatments were evident post treatment recording. At 2 months, PPD was reduced to 4.52 mm in the SRP alone group, to 5.27 in SRP plus chitosan, to 5.60 mm in the SRP plus Salvadora Persica chip group and to 4.63 mm in the SRP plus BITC chip group contrasted with pre-treatment records.

Secondary outcome measures
For bleeding on probing, the outcome shows that there was significant improvement in bleeding on probing in all groups post treatment. The enhancements in BOP were comparatively similar for all groups following 2 months (p=0.05).

Overall study start date
25/04/2011

Completion date
30/12/2011

Eligibility

Key inclusion criteria
1. Twelve chronic periodontitis male aged between 35 and 56 years (mean age 41.8 ± 5.6)
2. Has at least 4 non adjacent teeth with periodontal pocket measuring ≥5mm

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
12

Key exclusion criteria

1. History of systemic disease that might impact the course of periodontal disease or would require prophylactic antibiotics before dental treatment
2. Antibiotics or any modality of periodontal treatment in the past 3 months
3. Presence of overhanging restorations
4. Pregnancy, smoking habits, allergy to Selvadora Persica (Miswak)

Date of first enrolment
25/04/2011

Date of final enrolment
30/12/2011

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Teknologi MARA
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Sponsor information

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Funder type
University/education

Funder Name
Universiti Teknologi MARA (Malaysia) ref: 600- RM I/ST/DANA5/3/ Dst (198/2009)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration