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Periodontal therapy in diabetic subjects

Submission date 12/06/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/06/2008	**Overall study status** Completed	
Last Edited 04/06/2019	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
005

Study information

Scientific Title

Efficacy of mechanical scaling and root planning and adjunctive chemotherapy (doxycycline hyclate 20 mg) on systemic health improvement in diabetics

Study objectives
To evaluate the effectiveness of scaling and root planning (SRP) and adjunctive chemotherapy (doxycycline hyclate 20 mg) on gingival health, specific cytokines and glycaemic control within diabetic subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee, Sultan Bin Abdulaziz Humanitarian City, Riyadh, Saudi Arabia

Study design
A double-masked, randomised, placebo-controlled, multi-centre trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Periodontal disease and diabetes mellitus

Interventions
The selected subjects were divided into four groups:

1. One session of SRP at baseline visit only, and placebo tablets 20 mg twice/day starting at baseline visit and continuing for 3 months only
2. One session of SRP at baseline visit only, and doxycycline hyclate (oral, 20 mg twice/day) starting at baseline visit and continuing for 3 months only
3. Two sessions of SRP, first at baseline visit and the second at 6-month visit, and placebo tablets 20 mg twice/day at baseline visit and 6-month visit continuing for 3 months from each visit
4. Two sessions of SRP, first at baseline visit and the second at 6-month visit, and doxycycline hyclate 20 mg twice/day at baseline visit and 6-month visit continuing for 3 months from each visit

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
doxycycline

Primary outcome measure
1. Effectiveness of SRP and adjunctive chemotherapy (doxycycline hyclate 20 mg) on gingival health. The following were assessed at baseline, 3, 6, 9 and 12 months:
1.1. Probing Pocket Depth (PPD)
1.2. Clinical attachment level (CAL)
1.3. Modified gingival index (MGI)
1.4. Plaque index (PI)
1.5. Bleeding on probing (BOP)

2. Effectiveness of SRP and adjunctive chemotherapy (doxycycline hyclate 20 mg) on specific cytokines and glycaemic control in diabetic subjects. Venous blood samples were obtained for laboratory analysis of cytokines (Tumuor Necrosis Factor alpha [TNF-a], Interleukine-1 alpha [IL-1 a]) and to evaluate glycated haemoglobin (HbA1c) for all subjects at baseline, 3, 6, 9 and 12 months.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/04/2006

Completion date
01/04/2007

Eligibility

Key inclusion criteria
1. Both males and females, age range 18-65 years old
2. Diabetes, identified as type 1 or 2
3. Have had diabetes for at least 1 year
4. Diabetes is under control by oral hypoglycemic agent or insulin or both
5. Have been on the same type and dose of diabetic medication for the past 6 months
6. Good physical condition with no serious medical conditions or transmittable disease i.e. malignant disease, active hepatitis, free from any cardiac condition that needs antibiotic prophylaxis prior to teeth scaling and root planning
7. Have minimum of 18 remaining natural and non-capped teeth
8. Have minimum of 6 sites in minimum of 2 different quadrants with probing pocket depth (PPD) >=5 mm but <=8 mm
9. Have not had treatment with SRP within 6 months prior to baseline visit
10. Visible supragingival calculus in minimum of 4 teeth in 2 different quadrants
11. Absence of orthodontic bands and brackets and/or dental appliances that would affect scored indices

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
500

Total final enrolment
346

Key exclusion criteria
1. Use of antibiotics within three months prior to baseline appointment
2. Pregnant or nursing female subjects

Date of first enrolment
01/04/2006

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Faisal Specialist Hospital and Research Centre
Riyadh
Saudi Arabia
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Sponsor information

Organisation
King Abdulaziz City for Science and Technology (Saudi Arabia)

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Sponsor type
Government

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ROR
https://ror.org/05tdz6m39

Funder(s)

Funder type
Government

Funder Name
King Abdulaziz City for Science and Technology, General Directorate of Research Grants Programmes (Saudi Arabia)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2010	04/06/2019	Yes	No