

Periodontal therapy in diabetic subjects

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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 (Tumour Necrosis Factor alpha [TNF- α], Interleukine-1 alpha [IL-1 α]) and to evaluate glycated haemoglobin (HbA1c) for all subjects at baseline, 3, 6, 9 and 12 months.

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

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

11536

Sponsor information

Organisation

King Abdulaziz City for Science and Technology (Saudi Arabia)

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

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