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Effect of diabetes mellitus on root canal disease

Submission date 12/06/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 15/06/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/06/2016	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Apical periodontitis (AP) is an acute or chronic dental condition where there is inflammation around the apex (tip) of a tooth root caused by a bacterial infection of the pulp of the tooth (soft tissue in the centre of the tooth). Research suggests that the microbes that cause the condition are quite similar to those that cause periodontal (gum) disease. Tooth pulp from patients with diabetes mellitis (DM) may suffer from a poor than usual blood supply and a poor than usual immune response. This means that DM patients are at increased risk of developing a pulp infection, pulp necrosis (pulp death) and toothache. A few studies have suggested that DM patients may be more prone to develop AP. However, findings have not yet confirmed if having DM affects success rate of root canal treatment compared to healthy people without DM. Furthermore, few studies have examined the effect of glycaemic control (control of blood sugar levels) on the prevalence of AP.The aim of this study is to look at the number of DM patients with AP compared to healthy non-diabetic people and examine the effect of glycaemic control on AP.

Who can participate?
Adult DM patients attending diabetes clinics at King Hussein Medical Centre and non-diabetic volunteers matched for age, gender and social class.

What does the study involve?
All participants are examined to see whether they suffer from AP using mouth panoramic x-rays. It is a one-time test and there is no follow-up.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
King Hussein Medical Center, Amman (Jordan)

When is the study starting and how long is it expected to run for?
November 2914 to September 2015

Who is funding the study?
King Hussein Medical Center, Amman (Jordan)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
201/5/2015

Study information

Scientific Title
Apical periodontitis and endodontic treatment in patients with type 2 diabetes mellitus: comparative cross sectional survey

Study objectives
The aim of this study was to investigate the prevalence of apical periodontitis (AP) in diabetic patients compared with matched non-diabetic patients and also to examine the effect of glycaemic control on the incidence of AP.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Observational

Study design
Comparative cross sectional survey

Study type(s)

Screening

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

Interventions
There are two groups of participants taking part in this trial; diabetic participants and non-diabetic control participants. All participants from both groups are evaluated for apical periodontitis using mouth panoramic x-rays. It is a one test setup with no follow-up.

Intervention Type
Other

Primary outcome(s)
Peri-apical status of tested teeth as an indication of periapical periodontitis, assessed via panoramic radiographs

Key secondary outcome(s)
Presence of endodontic treatment of tested teeth and success of treatment as assessed by the peri-apical index (PAI) score

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Diabetic patients attending diabetes clinics at King Hussein Medical Centre
2. Age, gender and social class-matched non-diabetic volunteers and participants who attended a family medicine clinic at the same hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Participants that do not fulfill the inclusion criteria

Date of first enrolment
01/04/2015

Date of final enrolment

30/09/2015

Locations

Countries of recruitment
Jordan

Study participating centre
King Hussein Medical Center
Amman
Jordan
111985

Sponsor information

Organisation
Jordan University

ROR
https://ror.org/05k89ew48

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
King Hussein Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request