

# Effect of diabetes mellitus on root canal disease

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<b>Registration date</b> 15/06/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/06/2016	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 mellitus (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 2014 to September 2015

### Who is funding the study?

King Hussein Medical Center, Amman (Jordan)

Who is the main contact?  
Dr Leena Smadi  
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## Contact information

**Type(s)**  
Public

**Contact name**  
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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

**Study design**  
Comparative cross sectional survey

**Primary study design**  
Observational

**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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	Participant information sheet				

