

# 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

Dr Leena Smadi

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**Participant information sheet**

No participant information sheet available

**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 measure**

Peri-apical status of tested teeth as an indication of periapical periodontitis, assessed via panoramic radiographs

**Secondary outcome measures**

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

**Overall study start date**

01/11/2014

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

300

**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

**Sponsor details**

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**Sponsor type**

University/education

**ROR**

<https://ror.org/05k89ew48>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

King Hussein Medical Centre

## **Results and Publications**

**Publication and dissemination plan**

**Intention to publish date**

01/08/2016

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Available on request