

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical, radiological, histological long term effects of Theracal in partial pulpotomy of human dental pulp

Protocol summary

Summary

The aim of this clinical case report study is to evaluate long term clinical, radiological and histological effects of Theracal in partial pulpotomy of human dental pulp. Theracal is a new light-cured resin-modified calcium silicate-filled material, which sets in 20 sec (Bisco Inc, Schamburg, IL, USA). Before the operative protocol a mandibular left Third molar of a 28 years old patient will be examined radiologically and clinically, then the tooth will be mechanically cleaned and disinfected with 0.2% chlorhexidine solution. After local Anesthesia and rubberdam application, occlusal class1 cavity will be prepared by a sterile round diamond bur. Bleeding of the exposed pulp will be controlled with saline irrigation and a sterile cotton pellet. Then Theracal will be prepared as a manufacture's recommendation and applied on exposure site and finally the tooth restores with glassionomer. Patient will be called back after one year for postoperative clinical and radiographical examinations and the tooth will be extracted for histological examinations. Inclusion criteria are: age (18-32), erupted third molar, closed apex, caries free, normal signs to vitality tests and exclusion criteria are: external or internal resorption and periapical lesion. The main outcome measure is pulp health and dentine barrier formation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041120004N4**
Registration date: **2016-05-25, 1395/03/05**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-25, 1395/03/05

Registrant information

Name

Hengameh Bakhtiar

Name of organization / entity

Islamic Azad University of Tehran, faculty of dentistry

Country

Iran (Islamic Republic of)

Phone

+98 912 813 2267

Email address

h_bakhtiar@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-12-31, 1393/10/10

Expected recruitment end date

2015-12-31, 1394/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical, radiological, histological long term effects of Theracal in partial pulpotomy of human dental pulp

Public title

Long term effects of Theracal in partial pulpotomy of human dental pulp

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria are: age (18-32), erupted third molar, closed apex, caries free, normal signs to vitality tests

and exclusion criteria are: external or internal resorption and periapical lesion. The main outcome measure is pulp health and dentine barrier formation

Age

From **18 years** old to **32 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **1**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Moral committee of islamic azad dental university of tehran

Street address

#10 Neyestan, Pasdaran Ave, Tehran, Iran

City

Tehran

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

0821.p.166.5

Health conditions studied

1

Description of health condition studied

Vital pulp therapy

ICD-10 code

IA49.1

ICD-10 code description

Infection disease

Primary outcomes

1

Description

Pulp health(sensitivity,pain)

Timepoint

Just after intervention,each month till one year

Method of measurement

Vitality test,cold test,EPT

2

Description

Sign of preapical pathology

Timepoint

Before intervention,before extraction

Method of measurement

Periapical radiography

Secondary outcomes

1

Description

Dentin bridge formation

Timepoint

One year after invention

Method of measurement

Histologic examination after tooth extraction

Intervention groups

1

Description

Before the operative protocol, the tooth will be radiologically examined to exclude the presence of caries or periapical pathology. Thermal testing and electric sensitivity testing will perform to assess pulp vitality. Before cavity preparation, the tooth will mechanically be cleaned and disinfected with 0.2% chlorhexidine solution. After local anesthesia (Septodont, Saint Maur des Fosses, France) and rubber dam application, occlusal Class I cavities will prepare by using round sterile diamond bur at high speed under air-distillated water spray coolant. An exposure of approximately 1.2 mm in diameter will be made with round carbide bur (4 1.2 mm) under sterile saline cooling. Bleeding will be controlled with saline irrigation, and a sterile cotton pellet is placed onto the pulp exposure site and will be capped with Theracal according to the manufacturer's recommendations. Theracal is a calcium silicate resin based material that cures in 20 seconds and is used for direct and indirect pulpcapping. It contains approximately 45% wt mineral material, 10% wt radiopaque component, 5% wt hydrophilic thickening agent and approximately 45% resin. The patent stated that the resin consists of a hydrophobic component such as urethane dimethacrylate, bisphenol A-glycidyl methacrylate, triethylene glycol dimethacrylate and a hydrophilic component such as hydroxyethylmethacrylate and polyethylene glycol dimethacrylate. After placing a 2 mm layer of Theracal paste and polymerization for 20 s,

the teeth will be provisionally restored with glass ionomer cement (GC).After a year after radio graphical and clinical examinations the tooth will be extracted and will be sent to a talented pathologist.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Islamic azad dental university

Full name of responsible person

Dr Hengameh Bakhtiar

Street address

#10 Neyestan, Pasdaran Ave, Tehran, Iran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic azad dental university

Full name of responsible person

Dr Hengameh Bakhtiar

Street address

#10 Neyestan, Pasdaran Ave, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic azad dental university

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic azad dental university

Full name of responsible person

Dr Hengameh Bakhtiar

Position

Endodontist

Other areas of specialty/work**Street address**

#10 Neyestan, Pasdaran Ave, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 8820 2705

Fax**Email**

H_bakhtiar@dentaliau.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic azad dental university

Full name of responsible person

Dr Hengameh Bakhtiar

Position

Endodontist

Other areas of specialty/work**Street address**

#10 Neyestan, Pasdaran Ave, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 8820 2705

Fax**Email**

H_bakhtiar@dentaliau.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Islamic azad dental university

Full name of responsible person

Fatemeh Abedi, Fereshteh Naghi Moosavi

Position

Endodontist

Other areas of specialty/work**Street address**

#10 Neyestan, Pasdaran Ave, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 8820 2705

Fax**Email**

H_bakhtiar@dentaliau.ac.ir

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol*empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*