# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparative evaluation of the clinical and immunological effects of photodynamic therapy as an adjunctive to scaling and root planing and scaling and root planing alone, in the treatment of moderate to severe chronic periodontitis.

## Protocol summary

**Summary**

The aim of this study was to evaluate the clinical and immunological effects of photodynamic therapy (PDT) as an adjunctive to scaling and root planing (SRP) on the cytokine profile and clinical parameters in moderate to severe chronic periodontitis. Material and method: A total of 24 patients (14 woman and 10 men) aged 18 to 70 years affected with moderate to severe chronic periodontitis were selected. In each quadrant one of the teeth with probing depth≥4mm was randomly treated with SRP (Control group) and the other was treated with SRP and PDT(Test group). Gingival cervical fluid samples were collected from the deepest part of the periodontal pocket of control and test teeth in baseline and after 3 month. Primary outcome variable include probing depth.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2012121611770N1**
Registration date: **2013-02-18, 1391/11/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2013-02-18, 1391/11/30

**Registrant information**

**Name**

Atabak Kashefimehr

**Name of organization / entity**

Tabriz University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 41 1335 5965

**Email address**

kashefimehra@tbzmed.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Tabriz University of Medical Sciences

**Expected recruitment start date**

2012-02-10, 1390/11/21

**Expected recruitment end date**

2012-11-06, 1391/08/16

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative evaluation of the clinical and immunological effects of photodynamic therapy as an adjunctive to scaling and root planing and scaling and root planing alone, in the treatment of moderate to severe chronic periodontitis.

**Public title**

Effect of photodynamic therapy on inflammatory biomarkers and clinical parameters in moderate to severe chronic periodontitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Moderate to severe Chronic periodontitis; existence of a minimum of 12 teeth in oral cavity with at least three natural teeth in four sites per

quadrant; ≥ 3mm of attachment loss in minimum of 30 percent of teeth; presence of at least one site with pocket depth of ≥ 4mm with bleeding on probing in per quadrant. Exclusion criteria: The ingestion of systemic antibiotics within the last one year, non-surgical periodontal treatment within the last 6 months; smoking; uncontrolled Diabetes; liver disease; malignancy; radiotherapy; pregnancy; females on estrogen therapy; allergic reactions to Toluidine blue.

**Age**
From **18 years** old to **70 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **24**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Tabriz university of medical sciences

**Street address**
Tabrize Dental Faculty, Golgasht street

**City**
Tabriz

**Postal code**
5166614711

**Approval date**
2012-12-22, 1391/10/02

**Ethics committee reference number**
91182

## Health conditions studied

### 1

**Description of health condition studied**
Chronic periodontitis

**ICD-10 code**
K05.3

**ICD-10 code description**
Chronic periodontitis

## Primary outcomes

### 1

**Description**
probing depth

**Timepoint**
after 3 month

**Method of measurement**
Periodontal probe

## Secondary outcomes

### 1

**Description**
Interleukin-1β level in gingival crevicular fluid

**Timepoint**
After 3 month

**Method of measurement**
ELIZA Kit

### 2

**Description**
TNF-alpha level in gingival crevicular fluid

**Timepoint**
After 3 month

**Method of measurement**
ELIZA Kit

### 3

**Description**
MMP-9 Level in gingival crevicular fluid

**Timepoint**
After 3 month

**Method of measurement**
ELIZA Kit

### 4

**Description**
MMP-8 Level in gingival crevicular fluid

**Timepoint**
After 3 month

**Method of measurement**
ELIZA Kit

## Intervention groups

### 1

**Description**
Intervention: Photodynamic therapy and scaling and root planing

**Category**
Other

## 2

**Description**
Control : Scaling and root planing alone
**Category**
Other

## Recruitment centers

## 1

**Recruitment center**
**Name of recruitment center**
Tabriz Dental Faculty, Department of Periodontics
**Full name of responsible person**
Dr. Atabak Kashefimehr
**Street address**
Golgasht Street,Tabriz Dental Faculty
**City**
Tabriz

## Sponsors / Funding sources

## 1

**Sponsor**
**Name of organization / entity**
Dental and Periodontal Research Center of the Tabriz University of Medical Sciences (Primary sponsor
**Full name of responsible person**
Dr. Reza Pourabbas
**Street address**
Tabriz Dental Faculty, Golgasht Street
**City**
Tabriz
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Dental and Periodontal Research Center of the Tabriz University of Medical Sciences (Primary sponsor
**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**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Tabriz university of medical sciences
**Full name of responsible person**
Dr. Atabak Kashefimehr
**Position**
Periodontist, Assistant professor
**Other areas of specialty/work**
**Street address**
Tabriz Dental Faculty, Golgasht Street
**City**
Tabriz
**Postal code**
5166614711
**Phone**
+98 41 1335 5965
**Fax**
+98 41 1334 6977
**Email**
Kashefimehra@tbzmed.ac.ir
Atabak.Kashefimehr@yahoo.com
**Web page address**
http://dentistryfac.tbzmed.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Tabriz university of medical sciences
**Full name of responsible person**
Dr. Atabak Kashefimehr
**Position**
Periodontist, Assistant professor
**Other areas of specialty/work**
**Street address**
Tabriz Dental Faculty, Golgasht Street
**City**
Tabriz
**Postal code**
5166614711
**Phone**
+98 41 1335 5965
**Fax**
+98 41 1334 6977
**Email**
Kashefimehra@tbzmed.ac.ir
**Web page address**
http://dentistryfac.tbzmed.ac.ir

## 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*