Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Assessing the effectiveness of systemic Tinidazole as an adjunct to non-surgical periodontal therapy in the treatment of chronic periodontitis in smokers

Protocol summary

Summary

Sixty smoker participants with a history of moderate to severe chronic periodontitis were selected from the population referred to the Department of Periodontics, international branch of Shiraz University of Medical Sciences. A detailed medical, periodontal, dental, and smoking history was obtained. Individuals who fulfilled the inclusion/exclusion criteria were invited to participate in the study. All eligible participants were thoroughly informed of the nature, potential risks, and benefits of their participation in the study and provided written informed consent. They were also informed about the known side effects of tinidazole and possible gastrointestinal disturbances. This study protocol was approved by the institutional ethical committee. The participants were randomly allocated to one of two groups .The control group consisted of 30 participants, and the test group had 30 participants. In both groups ages be matched with each other. Before scaling and root planning , Strict oral hygiene instructions (OHI) were instituted on all participants at the same time by the operator .then GI Leo and Silness ، PI Oleary ، BI Lenox ، Attachment level ، Recession ، PD measured by use of Williams probe. Recession and PD recorded in all present teeth in six sites (mesio-buccal, midbuccal, disto-buccal, mesio-palatal/lingual, mid-palatal/ lingual, and disto-palatal/lingual) in each patient of both groups by the same person. Disclosing tablets was used for evaluating PI in four surfaces of teeth (mesial, distal, buccal,lingual/palatal).BI lenox was measured in four sites (mesial, distal, mid buccal and mid palatal/lingual) in all present teeth. GI index evaluated in six teeth (mandibular first molar, first premolar, central incisors and maxillary first molar, first premolar and central incisors). Next, the operator treated the periodontal disease with SRP. After this, each participant received a package containing the test or placebo medication; all packages were identical in appearance and were marked only with the participant number. Participants in the test group received 2g tinidazole as loading dose in the first day and then participants in the test group received 500 mg tinidazole to be taken once daily for 6 days. Participants in the control group received similar looking placebos prepared at the College of Pharmacy, Shiraz. The treatment group was masked from the patient, clinical examiner, operator, and statistician. Clinical Monitoring: all the participants in both groups were recalled at 6 weeks after the baseline visit. Clinical parameters, including PI, GI, PD, Recession ,BI and CAL, were recorded at these time intervals. OHI were checked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015022521195N2**
Registration date: **2015-06-29, 1394/04/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-29, 1394/04/08

Registrant information

Name

Armaghan Tarjan

Name of organization / entity

ib branch of Shiraz University

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source
Shiraz University of Medical Sciences

Expected recruitment start date
2014-12-22, 1393/10/01
Expected recruitment end date
2015-04-26, 1394/02/06
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the effectiveness of systemic Tinidazole as an adjunct to non-surgical periodontal therapy in the treatment of chronic periodontitis in smokers

Public title
The effectiveness of systematic tinidazole in the treatment of periodontitis in smokers
Purpose
Treatment
Inclusion/Exclusion criteria
sixty systemically healthy individuals with untreated moderate-to-advanced periodontitis were recruited into the study based on the following criteria: 1)patients do not use antibiotics in last 2 months. 2)do not have periodontal disease in last 6 months. 3)do not have systematic disease including: diabetes, hypertension, heart disease and other infectious diseases 4)participants should be current smokers(are defined as persons who had smoked at least 100 cigarettes in their lifetime and reported that they were smoking at the time of interview. Exclusion criteria: 1) pregnancy or lactation; 2) systemic diseases (such as diabetes mellitus); 3) systemic antibiotics taken within the previous 2 months; 4) use of non-steroidal anti-inflammatory drugs; 5) confirmed or suspected intolerance to 5-nitroimidazole derivatives; and 6) subgingival SRP or surgical periodontal therapy in the previous 6 month.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Participants in the test group received 2g tinidazole as loading dose in the first day and then Participants in the test group received 500 mg tinidazole to be taken once daily for 6 days. Participants in the control group received similar looking placebos prepared at the College of Pharmacy ,shiraz. The treatment group was masked from the patient, clinical examiner, operator, and statistician. Student’s t test was the statistical test used for comparing differences in PI, BI,GI, PD, Recession and CAL between the two groups .To compare the differences in various parameters within each group, paired t test was used. The level of significance (a) was taken as 0.05, and the confidence intervals (CIs) were set at 95%. P <0.05 was taken as statistically significant.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences, International Branch
Street address
Dentistry department, Valiasr square, next to the Nader Kazemi clinic
City
Shiraz
Postal code
14111-71546
Approval date
2014-10-11, 1393/07/19
Ethics committee reference number
8893086

Health conditions studied

1

Description of health condition studied
Moderate to advanced periodontitis in smokers
ICD-10 code
XXI
ICD-10 code description
Factors influencing health status and contact with health services

Primary outcomes

1

Description
GI Leo and Silness was measured
Timepoint
Baseline visit and six weeks later

Method of measurement
According to the color of gingiva and use of probe

2

Description
PI Oleary was measured
Timepoint
Baseline visit and six weeks later
Method of measurement
By disclosing tablet

3

Description
Before scaling and root planning , Strict oral hygiene instructions (OHI) were instituted on all participants at the same time by the operator.
Timepoint
Baseline visit and six weeks later
Method of measurement
Measured by use of Williams probe. Recession and PD recorded in all present teeth in six sites (mesio-buccal, midbuccal, disto-buccal, mesio-palatal/lingual, mid-palatal/ lingual, and disto-palatal/lingual) in each patient of both groups by the same person.disclosing tablets was used for evaluating PI in four surfaces of teeth(mesial, distal, buccal,lingual/palatal).BI lenox was measured in four sites (mesial, distal, mid buccal and mid palatal/lingual) in all present teeth.GI index evaluated in six teeth(mandibular first molar,first premolar ,central incisors and maxillary first molar ,first premolar and cetral incisors)

4

Description
BI Lenox was measured
Timepoint
Baseline visit and six weeks later
Method of measurement
By using probe

5

Description
Attachment level was measured
Timepoint
Baseline visit and six weeks later
Method of measurement
PD+ recession

6

Description
Recession was measured
Timepoint
Baseline visit and six weeks later
Method of measurement
By using probe

7

Description
PD measured
Timepoint
Baseline visit and six weeks later
Method of measurement
By probing

Secondary outcomes

empty

Intervention groups

1

Description
In the control proup after measuring the indexes and doing SRP we give placebo to the patiants ,for the first day 4 tablets then thy use 1 tablet per day for 6 days
Category
Placebo

2

Description
Participants in the intervention group received 2g tinidazole as loading dose in the first day and then Participants in the test groupreceived 500 mg tinidazole to be taken once daily for 6 days..
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz University of Medical Sciences, International Branch
Full name of responsible person
Armaghan Tarjan
Street address
Nader Kazemi clinic, Valiasr square
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences, International Branch
Full name of responsible person
Dr. Farin Kiany
Street address
Dentistry department, Ghom abad
City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences, International Branch

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

Shiraz University of Medical Sciences, International Branch

Full name of responsible person

Armaghan Tarjan

Position

Dentistry student

Other areas of specialty/work

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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