Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effect of two drugs acetaminophen codeine and Anahil in combination with acetaminophen codeine on pain relief in patients needing dental implants after implant surgery

Protocol summary

Study aim
The present study will be conducted with the aim of comparing the pain relief of two drugs Anahil and acetaminophen codeine on pain after implant surgery.

Design
Clinical trial with control group, with parallel groups, single-blind, randomized, phase 2 on 60 patients.

Settings and conduct
The studied population are adult patients in need of dental implants referred to the Faculty of Dentistry of Shiraz University of Medical Sciences. At first, the researcher will select 60 patients who meet the criteria for inclusion in the study, and an informed consent form will be completed for all patients. In the future, all patients will undergo implant surgery. Then, after the completion of the implant surgery, in the second stage, using a simple randomization method, the patients are divided into two intervention groups and the control group. Medical treatment for three days every 8 hours starts 30 minutes after the completion of implant surgery. The patient and the researcher who will give the drugs to the patient are blinded. Finally, the amount of pain in patients 1, 3 and 7 days after implant surgery will be measured and compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients in need of implant placement Exclusion criteria: taking painkillers before implant surgery

Intervention groups
Intervention group: taking Anahil in combination with acetaminophen every 8 hours for three days after surgery Control group: taking acetaminophen alone every 8 hours for three days after surgery

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230221057473N1**
Registration date: **2023-04-26, 1402/02/06**
Registration timing: **prospective**

Last update: **2023-04-26, 1402/02/06**
Update count: **0**

Registration date
2023-04-26, 1402/02/06

Registrant information

Name
Reza Hoseinzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3228 5806

Email address
reza.2016.hoseinzadeh95@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-30, 1402/02/10

Expected recruitment end date
2023-05-20, 1402/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of two drugs acetaminophen codeine and Anahil in combination with acetaminophen codeine on pain relief in patients needing dental implants after implant surgery

Public title
The effect of Anahil drug on pain relief after dental implant implantation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients needing implants Age above 20 years Absence of systemic disease

Exclusion criteria:
Patients who had taken painkillers or other drugs within 24 hours before surgery. They had a history of addiction to drugs or painkillers. Patients who were pregnant or breastfeeding, or had a known sensitivity to analgesics, nonsteroidal anti-inflammatories, or cyclooxygenase-2 inhibitors.

Age
From **20 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomize in this study, simple randomization method will be used. Randomization will be done using a sealed envelope containing a bead. If there is a white bead in the envelope, the patient will be in the intervention group, and if the envelope contains a red bead, he will be placed in the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the drugs, the study will be double-blind. Considering that the intervention group receives two drugs and the control group receives only one drug, the intervention and control groups must be blind to the type of treatment. Patients receive the medicine in closed envelopes with black cover that are coded (A and B). Coding is done by one of the collaborators of the project, and the researcher who will give the drugs to the patient does not know the nature of the drug inside the envelope.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Qasr al-Dasht street, Qomabad

City
Shiraz

Province
Fars

Postal code
15878-71956

Approval date
2023-02-04, 1401/11/15

Ethics committee reference number
IR.SUMS.DENTAL.REC.1401.129

Health conditions studied

1

Description of health condition studied
Patients needing dental implants

ICD-10 code
.

ICD-10 code description
.

Primary outcomes

1

Description
pain

Timepoint
1, 3 and 7 days after implant surgery

Method of measurement
visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: taking Anahil 500 mg along with acetaminophen codeine (300 mg acetaminophen + 20 mg codeine)Salamat Parmoun Amin Pharmaceutical Company every 8 hours for three days at 30 minutes after the completion of implant surgery.

Category

Treatment - Drugs

2

Description
Control group: taking acetaminophen codeine (300 mg acetaminophen + 20 mg codeine) alone Salamat Parmoun Amin Pharmaceutical Company every 8 hours for three days at 30 minutes after the completion of implant surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Shiraz University of Medical Sciences
Full name of responsible person
Sheila Shahsavaripour
Street address
Qasr al-Dasht St. - Qomabad
City
Shiraz
Province
Fars
Postal code
15878-71956
Phone
+98 71 3626 3193
Email
sheilashahsavaripour@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Research assistant
Street address
Qasr al-Dasht St. – Qomabad
City
Shiraz
Province
Fars
Postal code
15878-71956
Phone
+98 71 3626 3193
Email
dental@sums.ac.ir
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
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Sheila Shahsavaripour
Position
assistant professor of oral and maxillofacial surgery
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Qasr al-Dasht St. – Qomabad
City
Shiraz
Province
Fars
Postal code
15878-71956
Phone
+98 71 3626 3193
Email
sheilashahsavaripour@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Sheila Shahsavaripour
Position
assistant professor of oral and maxillofacial surgery
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Qasr al-Dasht St. – Qomabad
City
Shiraz
Province
Fars
Postal code
15878-71956

Phone
+98 71 3626 3193
Email
sheilashahsavaripour@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Sheila Shahsavaripour
Position
assistant professor of oral and maxillofacial surgery
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Qasr al-Dasht St. – Qomabad
City
Shiraz
Province
Fars
Postal code
15878-71956
Phone
+98 71 3626 3193
Email
sheilashahsavaripour@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
.
When the data will become available and for how long
.
To whom data/document is available
no
Under which criteria data/document could be used
.
From where data/document is obtainable
.
What processes are involved for a request to access data/document
.
Comments