Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of Acetaminophen-Ibuprofen combination on pain relief following primary tooth extraction regarding the prescription time in 6-12 year old children in Kerman,Iran

Protocol summary

Study aim

Comparison of effect of Acetaminophen-Ibuprofen combination on pain relief following primary tooth extraction regarding the prescription time

Design

In this blinded clinical trial study,120 patients will be classified to four group randomly. In first group, placebo 1 hour before extraction, second group, placebo 1 hour after extraction, third group; Acetaminophen-Ibuprofen combination 1 hour before extraction and the fourth group, Acetaminophen-Ibuprofen combination 1 hour after extraction will be given.

Settings and conduct

In this blinded clinical trial study,120 children from children who will be referring to the Pediatric Department of Kerman dentistry university, they will be classified in four group randomly. In first group, placebo 1 hour before extraction, second group,placebo 1 hour after extraction, third group, Acetaminophen-Ibuprofen combination 1 hour before extraction and the fourth group, Acetaminophen-Ibuprofen combination 1 hour after extraction will be indicated.Then according to visual analogue scale(VAS) child,s pain will be recorded immediately after extraction,30 minutes,6 hours and 24 hours later.

Participants/Inclusion and exclusion criteria

6-12 year old children with no systemic disorder. They have one primary hopeless molar with at least 1/3 root length. Children have sufficient physical and mental development and also be cooperative.

Intervention groups

In control group, placebo(Neurobion forte-vit B Complex-vit B12) in two isolated group, one group 1 hour before extraction and the another one, 1 hour after extraction will be given. In intervention group, Acetaminophen-Ibuprofen combination in two groups, 1 hour before extraction and the another one, 1 hour after extraction will be indicated.

Main outcome variables

pain alleviation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180521039763N3**
Registration date: **2019-09-04, 1398/06/13**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-04, 1398/06/13**
Update count: **0**

Registration date

2019-09-04, 1398/06/13

Registrant information

Name

Fatemeh Jahanimoghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 8071

Email address

jahanimoghadam@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-21, 1398/04/30

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Acetaminophen-Ibuprofen combination on pain relief following primary tooth extraction regarding the prescription time in 6-12 year old children in Kerman,Iran

Public title
The effect of Acetaminophen-Ibuprofen combination on pain relief regarding the prescription time
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
6-12 year- old children Without any systemic diseases The children have sufficient physical growth and mental development. Be cooperative
Exclusion criteria:
Children with liver,renal,gastric disorders and colitis History of corticosteroid or/and pain reliever use in recent 24 hours.
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The Random allocation rule has been used.(Reference:Mohammadi M, Janani L. Randomization in randomized clinical Trials: from theory to practice). Based on the number of participants, provide one form and we have 120 forms totally which putting in on file.Then according to the patient entrance, one of the forms will be raised consecutively.
Blinding (investigator's opinion)
Double blinded
Blinding description
Acetaminophen-Ibuprofen combination or placebo(Neurobion forte-vit B Complex vita B12) in form of syrup will be given to each group. Each child will have a code and will be known with this code in information form. Analyzer will analysis data according to these codes.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman university of medical
Street address
Shafa Ave, Jomhuri Blvd
City
Kerman
Province
Kerman
Postal code
7619813159
Approval date
2019-02-23, 1397/12/04
Ethics committee reference number
478.IR.KMU.REC.1397.

Health conditions studied

1

Description of health condition studied
The effect of Acetaminophen-Ibuprofen combination on relieving pain before and after extraction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
pain relief rate
Timepoint
Immediately after extraction until the next 24 hours
Method of measurement
According to Visual Analigue Scale(VAS)

Secondary outcomes

1

Description
The effect of age,gender on Acetaminophen-Ibuprofen combination
Timepoint
During filling the questionare
Method of measurement
Age will be calculated according to birth year/Gender aacording to observation

Intervention groups

1

Description

Intervention group: First group, 1 hour before extraction, dose of Acetaminophen-Ibuprofen will be indicated according to exact weight which will be calculated with digital scale .(Personal Scale Business counting Digital Scale,KG180) Ibuprofen suspension(Ibuprofen,Alborzrdarou Co,Iran 100mg/5ml Susp) in dose of 2.5mg/kg and Acetaminophen syrup(Acetaminophen, syrup,60mg/5ml, Ramofarmin Co,Iran)in dose of 7.5mg/kg will be calculated. Second group: 1 hour after extraction, dose of Acetaminophen-Ibuprofen combination similar to first group will be calculated and indicated.

Category

Treatment - Drugs

2

Description

Control group:First group, placebo as syrup(Neurobion forte-vit B lComplex vita B12, OTC Pharmaceutical Products. www.otcpharmausa) 16 Oz,/ 473ml with the same dose of Acetaminophen-Ibuprofen combination will be indicated one hour before extraction.Second group: one hour after extraction will be given.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman Dentistry University

Full name of responsible person

Mahboobeh Shokrizadeh

Street address

Shafa Ave, Jomhuri Blvd

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 3211 3498

Email

sit@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhti

Street address

Shafa Ave, Jomhuri Blvd

City

Kerman

Province

Kerman

Postal code

7618819949

Phone

+98 34 3211 3498

Email

sit@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Jahanimoghadam

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Shafa Ave, Jomhuri Blvd

City

Kerman

Province

Kerman

Postal code

7618819949

Phone

+98 34 3211 8071

Email

Fatemehjahani4@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person
Fatemeh Jahanimoghadam
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shafa Ave, Jomhuri Blvd
City
Kerman
Province
Kerman
Postal code
7618819949
Phone
+98 34 3212 7557
Email
Fatemehjahani4@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Jahanimoghadm
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shafa Ave, Jomhuri Blvd
City
Kerman
Province
Kerman
Postal code
7618819949
Phone
+98 34 3212 7557
Email
fatemehjahani4@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data is shared by non-identifiable participants
When the data will become available and for how long
6 months after printing result
To whom data/document is available
People working in academic centers
Under which criteria data/document could be used
The use of information is permitted for more comprehensive research
From where data/document is obtainable
Shokrizadeh Mahboobeh, Jahanimoghadam Fatemeh
What processes are involved for a request to access data/document
After reviewing the request masseage, information is provided to them
Comments