Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 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)

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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

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7618759689

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
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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

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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