

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparative Study of Acetaminophen, Ibuprofen and Combination Effects for Pain Relief Following Tooth Extraction in Children under Local Anesthesia

Protocol summary

Summary

It is clear that tooth extraction is painful. Our purpose is to compare the effects of acetaminophen, ibuprofen and combination of them in relieving the teeth pain due to extraction under local anesthesia. In this randomized clinical trial, 105 children (6-11 years old) referred to pediatrics ward of dental faculty of Hamadan University, after taking a testimonial from their parents and taking a history and weighing them, randomly allocated to three groups of 35. Group 1 received acetaminophen syrup with dose of 15mg/kg. Group 2 received ibuprofen syrup with dose of 5 mg/kg and group 3 received acetaminophen syrup with dose of 7.5mg/kg and ibuprofen syrup with dose of 2.5mg/kg. These children randomly pick out one of the paper written in advance. One hour before and 15 min after tooth extraction, amount of their pain are evaluated according to table (CHEOPS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103123109N2**

Registration date: **2011-04-21, 1390/02/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-21, 1390/02/01

Registrant information

Name

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Name of organization / entity

Hamadan Medical University

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Recruitment status

Recruitment complete

Funding source

Hamadan Medical University

Expected recruitment start date

2008-08-22, 1387/06/01

Expected recruitment end date

2009-08-23, 1388/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study of Acetaminophen, Ibuprofen and Combination Effects for Pain Relief Following Tooth Extraction in Children under Local Anesthesia

Public title

pain reduction in dentistry

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 6-11 years old, referred to dental clinic for first time, the mooler tooth must be extracted

Exclusion criteria : any disease such as asthma, hypersensitivity or allergy to drugs

Age

From **6 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 105

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

Research Ethics committee of Hamadan University of Medical Sciences

Street address

Hamadan Medical University

City

Hamadan

Postal code

Approval date

2008-05-19, 1387/02/30

Ethics committee reference number

16/35/9/27510

Health conditions studied

1

Description of health condition studied

teeth pain due to extraction

ICD-10 code

Y45

ICD-10 code description

Analgesic, antipyretic and antiinflammatory drugs

Primary outcomes

1

Description

pain

Timepoint

0 and 15 min after tooth extraction

Method of measurement

Children's Hospital of Eastern Ontario Pain Scale(CHEOPS)

Secondary outcomes

empty

Intervention groups

1

Description

group 1 received acetaminophen syrup 15mg/kg one hour before tooth extraction

Category

Treatment - Drugs

2

Description

Group 2 received ibuprofen syrup 5mg/kg one hour before tooth extraction

Category

Treatment - Drugs

3

Description

Group 3 received acetaminophen 7.5 mg/kg and ibuprofen syrup 2.5mg/kg one hour before tooth extraction

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan University of Medical Science

Full name of responsible person

Street address

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Science

Full name of responsible person

Dr Ghaleiha

Street address

Medical School, Deputy dean for Research

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamadan University of Medical Science
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

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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