

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the Effect of Honey on the Healing of Tooth Extraction Wounds in 4-6-year-old Children

Protocol summary

Study aim

evaluation the effect of honey on tooth extraction wound healing in children 4–9 years of age.

Design

clinical trial with control group, with parallel groups and randomized

Settings and conduct

This study is a randomized clinical trial. In this study, 51 patients aged 4 to 9 years who referred to the pediatric department of Dental School of Tehran University of Medical Sciences who needed to remove a primary molar were randomly assigned to the study. The children were then randomly divided into two groups. In the first group, after dental extraction, the dentist placed a layer of honey on the wet gel and with the help of the applicator, and the gas was placed on socket, and the second group did not use honey. On the third and seventh day after extraction, the size of the ulcers was measured using a digital caliper and the result was multiplied by the two number ultimate wound sizes.

Participants/Inclusion and exclusion criteria

children 4–9 years of age

Intervention groups

after tooth extraction a dentist paced a 1-mm layer of honey with the use of an applicator on a piece of gauze moistened with normal saline solution. The honey was freshly acquired from the Iranian Kurdistan Mountains. The honey was placed in contact with the socket wound. Then the parents and children were asked to keep the gauze piece in place for 45 minutes.

Main outcome variables

wound size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181008041269N1**

Registration date: **2018-11-05, 1397/08/14**

Registration timing: **retrospective**

Last update: **2018-11-05, 1397/08/14**

Update count: **0**

Registration date

2018-11-05, 1397/08/14

Registrant information

Name

Saeedeh Mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4279 4200

Email address

sa.mokhtari@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

2017-03-21, 1396/01/01

Actual recruitment end date

2017-06-22, 1396/04/01

Trial completion date

2017-07-23, 1396/05/01

Scientific title

Evaluation of the Effect of Honey on the Healing of Tooth Extraction Wounds in 4-6-year-old Children

Public title

effect of honey on wound healing

Purpose

Treatment

IR.TUMS.VCR.REC.1395.1951

Inclusion/Exclusion criteria

Inclusion criteria:

no history of systemic conditions, use of medications and allergy to honey not repeatedly used honey during the previous 6-month period. need removal of one deciduous molar tooth,

Exclusion criteria:

Any systemic conditions that prevent dental treatment under local anesthesia A history of allergy to the substance of anesthesia and sulfate and honey

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Actual sample size reached: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

simple After reviewing the inclusion and exclusion criteria, each patient randomly using simple randomization and individual (open envelope sealed) divided into two groups of treated with honey and without honey

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of dental school of Tehran university of medical sciences

Street address

North Kargar St.

City

Tehran

Province

Tehran

Postal code

1439955934

Approval date

2017-03-12, 1395/12/22

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

wound healing

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

wound size decrease

Timepoint

seven days

Method of measurement

using digital caliper

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: applying a piece of gauze moistened with normal saline solution and a thin layer (1mm thick) fresh Kordestan honey for 45 min

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Pediatric, Dentistry Dental school, Tehran university of medical sciences

Full name of responsible person

Saeedeh Mokhtari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

دکتر مرضیه علی خاصی

Street address

amirabad st.

City

tehran

Province

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1439955991

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smokhtari@sina.tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Saeedeh Mokhtari

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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