Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of honey on wound healing and prevention of surgical site infection in patients with cleft lip

Protocol summary

Summary

Objectives: cleft lip is a congenital disorder in which prompt repair and scar prevention together can result in early improvement and thus give reassurance to the parents. Honey as a cheap and accessible natural material can be used to dress wounds in these patients. Method: forty children with cleft lip who had undergone surgical management were selected. After surgical repair a tube containing sterile gel (honey or placebo) were given to parents to apply on the wound. Placebo was carbomer 953 which is indistinguishable from honey and has no good or bad effect on the wound. Participants: patients with bilateral and unilateral cleft lip were included. Any disorder which could result in wound improvement delay and children with metabolic disease were excluded from the study. Interventions: All patients in both groups were on antibiotics post surgery and this study did not deprived subjects from routine treatments. Honey or placebo was applied to the wound as a thin layer three times a day for a two week period. The used honey was the Iranian honey from Azerbaijan territory which was reproduced as a Gel by the second author in Tabriz pharmacy school. Considering the probable Clostridium botulinum infection, the honey was sterilized with radiation by Tehran atomic energy organization and tested for quality control after radiation. The primary result: patients' wound was examined on 1st, 2nd, 7th, 14th, 21st and 30th day after surgery and relevant data such as color, shape, size and amount of scar formation was recorded

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030316809N1**
Registration date: **2014-07-30, 1393/05/08**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-07-30, 1393/05/08

Registrant information

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Shahin Abdollahifakhim
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Pharmaceutical Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of honey on wound healing and prevention of surgical site infection in patients with cleft lip

Public title

The effect of honey on wound healing and prevent infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Isolated unilateral or bilateral cleft lip 2- Non genetic syndromes 3- Non Cyanotic congenital heart disease, severe respiratory disease, kidney disease and other disorders affecting the wound healing process Exclusion criteria: 1- Splitting wounds due to trauma 4- Severe Infectious disease (sepsis) 5- Severe malnutrition 6- Allergy to Honey

Age

From **1 year** old to **2 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

non

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

University St.

City

Tabriz

Postal code

5136735886

Approval date

2013-08-22, 1392/05/31

Ethics committee reference number

5/4/4478

Health conditions studied

1

Description of health condition studied

Effectiveness of honey in wounds repairing process

ICD-10 code

Q36.9

ICD-10 code description

Cleft lip NOS

Primary outcomes

1

Description

Surgical Wound infection of Cleft Lip Repair

Timepoint

2 weeks after intervention

Method of measurement

Clinical assessment

2

Description

Surgical Wound healing of Cleft Lip Repair

Timepoint

two weeks after intervention

Method of measurement

clinical assessment

Secondary outcomes

empty

Intervention groups

1

Description

Applied honey was Iranian pure honey from Azarbaaijan region, which was prepared as a gel by second author in college of pharmacy, Tabriz University of medical science. In this project, due to the possibility of Clostridium botulinum in honey, radiation was done for sterilization of honey with keep useful material in Tehran's atomic energy agency after determining the dose of radiation and after assuring the quality of the honey, Re-examined by the appropriate agency. For two weeks, three times a day with sterile honey applied as a thin layer on the suture site.

Category

Treatment - Other

2

Description

We used Carbomer 953 as a Placebo that looks like honey and had no beneficial or detrimental effect on ulcers and are filled similar tubes and for two weeks, three times a day with sterile the placebo applied as a thin layer on the suture site.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Children Hospital of Tabriz University of Medical Sciences

Full name of responsible person
Shahin Abdollahifakhim

Street address
University St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Office of the Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences

Full name of responsible person
Mahdi Farhoudi

Street address
University St.

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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
Office of the Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences

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

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Shahin Abdollahifakhim

Position
Assistant Professor of ENT

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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