Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial the effect of spring honey on healing of foot ulcer in diabetic patients

Protocol summary

Summary

The aim of this study is the evaluation of Honey effect on wound healing in diabetic foot. This study population included all patients admitted to Sari Hekmat hospital with diabetic foot. Inclusion criteria include having diabetic foot type 2 and 3 and the absence of vascular disease and exclusion criteria are rheumatoid arthritis, vasculitis, chemotherapy, immunosuppressive and steroid drugs. Data will be collected using list. wound will be assessed whit a list include grade, depth and length of lesion, pain severity, infection and the type of microorganisms before study and at the end of the first, second and third week after intervention. Debridement will be performed for all patients that are required by orthopedic surgeon under general or regional anesthesia. Daily dressing will be performed after washing the wound with normal saline. Then with a piece of gauze that is about 2 cm larger than the size of the wound , honey will be applied , and the wound will be dressing. In the control group after washing the wound with normal saline, a layer of sock gauze will be applied on wound and with minimal pressure the wound will be bandaged. Wound dressing will be done daily with a trained nurse and control of it's recovery will be followed by orthopedic surgeon. At the end of the first, second and third week wound will be assessed. Data will be analyzed using SPSS software version 16.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402207494N8**
Registration date: **2014-05-26, 1393/03/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-26, 1393/03/05

Registrant information

Name
Masoumeh Bagheri Nesami
Name of organization / entity
Mazandaran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 11 3336 7551
Email address
mbagheri@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Mazandaran University of Medical Sciences, Moalem Street ,Moalem Square,Sari, Iran.

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial the effect of spring honey on healing of foot ulcer in diabetic patients

Public title

Honey on healing of foot ulcer in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ulcer diabetic type 2 and 3 ; absence of vascular disease Exclusion criteria; rheumatoid arthritis, vasculitis, chemotherapy, immunosuppressive and steroid drugs drugs affecting the nerves and blood vessels, such as anticonvulsants and anti-arrhythmias

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Ethics Committee of Mazandaran University of Medical Scienc, Imam Square, Highway Bassij, 3-way Jouibar, Sari, Mazandaran

City

Sari

Postal code

4815696869

Approval date

2014-02-20, 1392/12/01

Ethics committee reference number

490

Health conditions studied

1

Description of health condition studied

diabetic foot ulcer

ICD-10 code

(I79.2*)

ICD-10 code description

Diabetic peripheral angiopathy

Primary outcomes

1

Description

Diiabetic foot ulcer

Timepoint

Befor study and at the end of the first, second and third week after intervention

Method of measurement

Researcher made list

Secondary outcomes

1

Description

Gangrene or amputation

Timepoint

Every day until the end of the study

Method of measurement

Assesment and report by a specialist nurse

Intervention groups

1

Description

In experimental group daily dressing will be performed after washing the wound with normal saline. Then with a piece of gauze that is about 2 cm larger than the size of the wound, honey will be applied, and the wound will be dressed. Spring honey that will be used in this study approved by food laboratory of Mazandaran University of Medical Sciences as PH, amount of Froctos and absence of micro-organisms .

Category

Treatment - Drugs

2

Description

In the control group after washing the wound with normal saline, a layer of sock gauze will be applied on wound and with minimal pressure the wound will be bandaged. Wound dressing will be done daily with a trained nurse and control of it's recovery will be followed by orthopedic surgeon.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Hekmat hospital

Full name of responsible person

Dr Masumeh Bagheri Nesami

Street address

School of Nursing & Midwifery, Vessal street, Sciences, Sari, Iran.

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research Mazandaran University of Medical Sciences.

Full name of responsible person

Dr Ahmad Ali Enayeti

Street address

Vice Chancellor for research Mazandaran University of Medical Sciences, Moalem Street ,Moalem Square,Sari, Iran..

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Attieh Nikkhah

Position

Master in critical care nursing

Other areas of specialty/work

Street address

School of Nursing & Midwifery, Vessal street, Sciences, Sari, Iran.

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4815696869

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atinik1357@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Social security organization

Full name of responsible person

Dr Shohre Pirzadeh

Position

Specialist in Orthopedics

Other areas of specialty/work

Street address

Hekmat hospital, Taleghani Ave,Sari, Iran.

City

Sari

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4815696869

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+98 32 68923

Fax

Email

atinik1357@yahoo.com

Web page address

Person responsible for updating data

Contact

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