

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effect of Cichorium intybus L. on change the liver enzymes in burn patients: a randomized double- blind placebo-controlled clinical trial

Protocol summary

Study aim

Evaluation the effect of Cichorium intybus L. on change the liver enzymes in burn patients

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

A study on burn patients hospitalized in Amirmomenin Hospital will be conducted; a double blinded study that neither patients nor researcher know about their reviving drug.

Participants/Inclusion and exclusion criteria

Patients in range of 20-75 years old that their burn duration is less than 2 days and burn percentage is 10%-50%; not intubated; do not have hepatitis, hyperlipidemia, history of seizure, and not pregnant.

Intervention groups

Intervention group: Cichorium intybus L is bought from market of medicinal plants. Once verified by the botanist, it is used to prepare herbal extracts. so the Cichorium intybus L is bold ten times the volume with water. For condensation, the rotary machine will be used and then converted to the powder by freeze-dried process. To make syrup, the powder is mixed with honey and other ingredients. After considering the appropriate formulation and having organoleptic properties suitable packaging is done. The dosage for patients will be equivalent to 6 grams of chicory seeds per day. Patients should take medication for a maximum of 4 weeks. Control group: chicory seeds will be provide With a much lower dose of the therapeutic dose.

Main outcome variables

The level of ALT, AST, Alb, CRP, creatinine and urea patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180609040016N1**

Registration date: **2018-06-18, 1397/03/28**

Registration timing: **prospective**

Last update: **2018-06-18, 1397/03/28**

Update count: **0**

Registration date

2018-06-18, 1397/03/28

Registrant information

Name

Abdolkhalegh Keshavarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3614 6521

Email address

keshavarzg@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Cichorium intybus L. on change the liver enzymes in burn patients: a randomized double-blind placebo-controlled clinical trial

Public title

Evaluation the effect of Cichorium intybus L. on change the liver enzymes in burn patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The burn time for patients is less than two days Their burn are is between 10% - 50% body surface percentage

Exclusion criteria:

The patients are not intubated No history for liver disease, hyperlipidemia, seizure No pregnancy

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is random balanced blocks with four sample in each block.

Blinding (investigator's opinion)

Double blinded

Blinding description

Neither the patient nor the researcher knows the nature of the drugs received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Ave., Shiraz

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.SUMS.REC.1396.194

Health conditions studied

1

Description of health condition studied

Liver disorder

ICD-10 code

76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

ALT level

Timepoint

Every 3 days until discharg

Method of measurement

Biochemistry analysis

2

Description

AST level

Timepoint

Every 3 days until discharg

Method of measurement

Biochemistry analysis

3

Description

Albumin level

Timepoint

Every 3 days until discharg

Method of measurement

Biochemistry analysis

4

Description

CRP level

Timepoint

Every 3 days until discharg

Method of measurement

Biochemistry analysis

5

Description

Creatinin level

Timepoint

Every 3 days until discharg

Method of measurement

Biochemistry analysis

6**Description**

Urea level

Timepoint

Every 3 days until discharg

Method of measurement

Biochemistry analysis

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: : Cichorium intybus L is bought from market of medicinal plants. Once verified by the botanist, it is used to prepare herbal extracts.so the Cichorium intybus L is bold Ten times the volume with water. For condensation, the rotary machine will be used and then converted to the powder by freeze-dried process. To make syrup, the powder is mixed with honey and other ingredients.After considering the appropriate formulation and having organoleptic properties suitable packaging is done.The dosage for patients will be equivalent to 6 grams of chicory seeds per day.Patients should take medication for a maximum of 4 weeks

Category

Treatment - Other

2**Description**

Control group: chicory seeds will be provide with a much lower dose of the therapeutic dose.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hospital of burn injury and wound healing of Amir al-Momenin

Full name of responsible person

Abdlokhalegh Keshavarzi

Street address

Training center for burn injuries amiralmomenin, Km 2 Sadra

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7198754361

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keshavarzi@sums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz 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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Abdlokhalegh Keshavarzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Rahimeh Akrami

Position

General physician

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Rahimeh Akrami

Position

General physician

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available