Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Investigating the effect of adding traditional medicine treatments (honey and frankincense extract) to common treatments on hyperuria in patients with diabetes insipidus in the intensive care unit -a preliminary study

Protocol summary

Study aim
Determining the effect of adding traditional medicine treatments to common treatments on hyperuria in patients with diabetes insipidus in the special care department of Golestan Hospital, Ahvaz in 1401

Design
Three arm parallel groups, double blind, randomised controlled trial. The groups include control group, intervention one group and intervention two group. Using rand function of excell software for randomization.

Settings and conduct
This research is carried out in the intensive care unit of Ahvaz Golestan Hospital on patients with neurogenic diabetes insipidus. control group, receive classic treatments for diabetes insipidus and placebo. intervention groups, in addition to classical treatments, receive a combination of honey and the extract of frankincense or ginger for 48 hours, then in all three groups, only classic treatments are continued. The patients, nurses and researchers do not know the type of compound used. The medicinal solution is prepared in a covered syringe and delivered to the nurse for gavage by pharmacist.

Participants/Inclusion and exclusion criteria
Inclusion criteria : hospitalization in the intensive care unit, having diagnostic criteria for diabetes insipidus
Exclusion criteria : interruption of enteral nutrition for any reason, declaration of non-consent by the patient's family

Intervention groups
In the control group, patients receive only classical treatments for diabetes insipidus (fluid therapy and desmopressin). In intervention group 1, in addition to classical treatments for diabetes insipidus, patients receive extracts of traditional medicines that include a combination of honey and frankincense. In the second intervention group, in addition to the classic treatments for diabetes insipidus, patients receive an extract of traditional medicines that includes a combination of honey and ginger.

Main outcome variables
24-hour office volume

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221121056570N1**
Registration date: **2022-12-29, 1401/10/08**
Registration timing: **prospective**

Last update: **2022-12-29, 1401/10/08**
Update count: **0**

Registration date
2022-12-29, 1401/10/08

Registrant information

Name
Mohsen Savaie

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-08-22, 1402/05/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of adding traditional medicine treatments (honey and frankincense extract) to common treatments on hyperuria in patients with diabetes insipidus in the intensive care unit -a preliminary study

Public title
Investigating the effect of adding traditional medicine treatments (honey and frankincense extract) to common treatments on polyuria in patients with diabetes insipidus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Hospitalization in the intensive care unit Having diagnostic criteria for diabetes insipidus Signing the informed consent form by the patient's family Establishment of enteral nutrition Not having drug interactions with the drugs received by the patient based on the opinion of traditional medicine pharmacist colleagues
Exclusion criteria:
Discontinuation of enteral feeding for any reason Death of the patient due to various causes Patient discharge Declaration of non-consent by the patient's family to continue the plan The occurrence of drug interactions with the drugs received by the patient based on the opinion of traditional medicine pharmacist colleagues
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **10**
intervention 1 (frankincense plus honey), intervention 2 (Ginger plus honey), Control (Placebo)
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment to intervention and control groups is done individually. All patients who have polyuria caused by diabetes insipidus in the intensive care unit will be included in the study after obtaining written informed consent if they meet the inclusion criteria and do not have the exclusion criteria. The patient is entered into one of the intervention 1, intervention 2 or control groups according to the order of entering the department, based on the blocks (n=6) of random numbers that were previously prepared by the statistical consultant with the software. The statistician who made the random blocks did not know how to assign treatment groups (control, intervention 1 or intervention 2).
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the participants (patient and his family), nurses, principal investigator, data collectors and outcome assessors are unaware of study group allocation. Allocating the control or intervention group to the cases and drawing the drug in the syringe is done by a person who is not among the researchers or nurses taking care of the patient.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Golestan Hospital Research
Street address
Ahvaz, Golestan, Golestan Hospital
City
ahvaz
Province
Khouzestan
Postal code
1579461357
Approval date
2022-10-18, 1401/07/26
Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1401.098

Health conditions studied

1

Description of health condition studied
neurogenic diabetes insipidus due to brain diseases or head injury
ICD-10 code
E23.2
ICD-10 code description
Diabetes insipidus

Primary outcomes

1

Description
Patient's urine volume during 24-hour
Timepoint
24-hour urine volume measurement at the beginning of the study (before the start of the intervention) and 24 and 48 and 72 hours after the administration of placebo, honey-frankincense or honey-ginger combination.
Method of measurement
24-hour urine volume measurement by graduated urine bags connected to the patient's Foley catheter daily (every 24 hours)

Secondary outcomes

1

Description
Serum sodium level
Timepoint
Serum sodium level measurement at the beginning of the study (before the start of the intervention) and 24 and 48 and 72 hours after the administration of placebo, honey-frankincense or honey-ginger combination
Method of measurement
Laboratory measurement on blood sample by biochemistry autoanalyzer

Intervention groups

1

Description
Intervention group 1: a group of patients who, receive traditional medicine including honey and frankincense extract as gavage every 12 hours for 48 hours in addition to classical treatments for diabetes insipidus, (10 ml of honey and 500 mg of frankincense extract dissolved in 20 ml of distilled water). Conventional treatments for diabetes insipidus include replacing the deficit of fluids with intravenous or oral solutions with minimal sodium (half saline, dextrose 5% or water) with a daily volume of approximately 4 ml per kilogram of body weight and reducing the volume of urine through the administration of Desmopressin (synthetic analogue of vasopressin) nasal spray 1-2 puff (10-40 microgram) every 12 hours and the treatment of primary brain disease.
Category
Treatment - Drugs

2

Description
Intervention group 2 : a group of patients who, receive traditional medicine every 12 hours for 48 hours including a combination of honey and ginger extract as gavage, in addition to the classical treatments for diabetes insipidus, (10 ml of honey and 500 mg of ginger extract dissolved in 20 ml of distilled water). Conventional treatments for diabetes insipidus include replacing the deficit of fluids with intravenous or oral solutions with minimal sodium (half saline, dextrose 5% or water) with a daily volume of approximately 4 ml per kilogram of body weight and reducing the volume of urine through the administration of Desmopressin (synthetic analogue of vasopressin) nasal spray 1-2 puff (10-40 microgram) every 12 hours and the treatment of primary brain disease.
Category
Treatment - Drugs

3

Description
Control group: a group of patients who only received classic treatments for diabetes insipidus, including replacement of body fluids through intravenous (half-saline fluid) and oral root at the rate of 4 ml per kilogram of body weight in 24 hours and desmopressin nasal spray (a synthetic analogue of vasopressin) under the brand of Minirin), 1 to 2 puffs (10 to 40 mg) every 12 hours. As a placebo, the patient receives a syringe containing 30 cc of water every 12 hours for 48 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
intensive care unit of Golestan Ahvaz Hospital
Full name of responsible person
Mohsen Savaie
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ahvaz 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
Ahvaz University of Medical Sciences
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Mohsen Savaie
Position
Assistant Professor
Latest degree
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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