Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Sep 2026

Comparison of the effect of aromatherapy and edible rose essential oil on saliva cortisol level and quality of life of chronic renal failure patients undergoing hemodialysis

Protocol summary

Study aim

Determining and comparison of the effect of aromatherapy and edible rose essential oil on saliva cortisol level and quality of life of chronic renal failure patients undergoing hemodialysis.

Design

Clinical trial without control group, with parallel groups, non-blind, randomized groups, 72 patients.

Settings and conduct

The studied population is hemodialysis patients referred to Shahid Beheshti and Shahid Jalil hospitals in Yasouj. After the approval of the research proposal by the Research Ethics Committee of Yasouj University of Medical Sciences, at the beginning of the study, questionnaires of demographic characteristics and short form of kidney disease quality of life will be completed and a saliva sample will be taken early in the morning. One month later, the patient's saliva will be collected again using ELISA kits to measure the salivary cortisol level and the short-form kidney disease quality of life questionnaire will be completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. At least three months have passed since hemodialysis. 2. Doing dialysis at least 2 to 3 times a week Exclusion criteria: 1. Allergy to Rosa damascene and patient reaction to it 2. Taking anti-anxiety and anti-depressant drugs

Intervention groups

The two intervention groups will be aromatherapy and oral intake. In aroma therapy group, when the patient is connected to the dialysis machine, a piece of cloth soaked in 3 drops of rose essence with a concentration of 2% is attached to the patient's collar and the patient will be asked to breathe normally. This work will be done 3 times a day and each time for 5 minutes for 4 weeks. In oral intake group when the patient is connected to the dialysis machine, 15 drops of rose extract will be poured into some water and every 8 hours given to him/her (3 doses in day).

Main outcome variables

Salivary cortisol levels and Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200610047725N1**
Registration date: **2023-04-18, 1402/01/29**
Registration timing: **retrospective**

Last update: **2023-04-18, 1402/01/29**
Update count: **0**

Registration date

2023-04-18, 1402/01/29

Registrant information

Name

Tahereh Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-03, 1399/07/12

Expected recruitment end date

2020-11-02, 1399/08/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of aromatherapy and edible rose essential oil on saliva cortisol level and quality of life of chronic renal failure patients undergoing hemodialysis

Public title

Comparison of the effect of aromatherapy and edible rose essential oil on saliva cortisol level and quality of life of chronic renal failure patients undergoing hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to communicate and answer questions Consent to participate in the study and sign the informed consent form Healthy sense of smell Not having an anxiety disorders Not having a history of using aromatherapy Not having asthma and allergies Not brushing teeth At least three months have passed since hemodialysis Doing dialysis at least 2 to 3 times a week Not taking corticosteroids and immunosuppressants Not having active infection Not having a history of organ transplant rejection Dialysis in the morning shift No history of cancer

Exclusion criteria:

Allergy to Rosa damascene and patient reaction to it Taking anti-anxiety and anti-depressant drugs Performing a kidney transplant during the study Change of dialysis method from hemodialysis to peritoneal dialysis during the intervention Hospitalization in the intensive care unit during the intervention

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants will be selected by purposive sampling from the available population and will be allocated through random block allocation to intervention group No.1 (aromatherapy) and intervention group No.2 (oral intake). In this way, by multiplying the number of studied groups (two groups) by 2, the number of samples of each block was calculated as 4. Then, through factorial calculation, the number of blocks resulting from all arrangement modes of people was calculated as 24 blocks (4! = 4 x3 x2 x1 = 24). Possible arrangement blocks of people will be A (gray dummy) for the intervention group No.1 (aromatherapy) and B (white dummy) for intervention group No.2 (oral intake). Since the number of people in each block is 4 people and the estimated sample size is 72 people, therefore by matching 18 random numbers generated by the Sample Randomizer software, The arrangement of people in the research sample and the allocation of each number from 1 to 72 to each one of the intervention group No. 1 (aromatherapy) and intervention group No. 2 (oral consumption) will be determined. Then the block random allocation list will be compiled. In the following, patients suffering from chronic renal failure under hemodialysis will be referred and qualified research samples will be selected by fully explaining the objectives of the study. Based on the priority of the referral, a code is assigned to each of them, and by matching that number with the random block allocation list, the patients participating in the research will be assigned to one of the groups of intervention number 1 (aromatherapy) and intervention number 2 (oral intake)) will be allocated. This process will continue until the estimated sample size is completed.

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 Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Iran.

City

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Province

Kohgilouyeh-va-Boyrahmad

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Approval date

2020-10-03, 1399/07/12

Ethics committee reference number

IR.YUMS.REC.1399.135

Health conditions studied

1

Description of health condition studied

Patients with chronic renal failure under hemodialysis

ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Salivary cortisol levels
Timepoint
Salivary cortisol levels at the beginning of the study (before the intervention) and one month later
Method of measurement
By ELISA kits

2

Description
Quality of life
Timepoint
Quality of life at the beginning of the study (before the intervention) and one month later.
Method of measurement
Kidney Disease Quality of Life-Short Form (KDQOL-SF) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group number 1 (aroma therapy): When the patient is connected to the dialysis machine, a piece of cloth soaked in 3 drops of rose essence with a concentration of 2% is attached to the patient's neck and the patient will be asked to breathe normally. This work will be done 3 times a day and each time for 5 minutes for 4 weeks.
Category
Treatment - Drugs

2

Description
Intervention group number 2 (oral intake): When the patient is connected to the dialysis machine, 15 drops of rose extract will be poured into some water every 8 hours and given to him/her. Totally, 3 doses of medicine will be given to the patient daily.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Yasouj 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
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Position
M.S student of medical-surgery nursing
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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