

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

+98 74 3322 1350

Email address

t60.taheri@gmail.com

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 ($4! = 4 \times 3 \times 2 \times 1 = 24$). 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

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591741417

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

Tahereh Taheri

Street address

Shahid Mohammad Montazeri St., Shahid Beheshti Hospital, Yasuj, Iran.

City

Yasuj

Province

Kohgiluyeh-va-Boyer-Ahmad

Postal code

7591794857

Phone

+98 74 3322 4721

Email

beheshtihospital@yasooj.ir

2

Recruitment center

Name of recruitment center

Martyr Dr. Jalil Hospital

Full name of responsible person

Tahereh Taheri

Street address

Martyr Dr. Jalil Hospital, Qarani Blvd., Yasuj, Iran.

City

Yasuj

Province

Kohgiluyeh-va-Boyer-Ahmad

Postal code

7591387493

Phone

+98 74 3333 7004

Email

t60.taheri@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Hossein Mari Oryad

Street address

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

City

Yasuj

Province

Kohgiluyeh-va-Boyer-Ahmad

Postal code

7591977833

Phone

+98 74 1333 7251

Fax

+98 74 3333 7230

Email
Oryad.hosseini@yums.ac.ir

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
Yasouj University of Medical Sciences

Full name of responsible person
Tahereh Taheri

Position
M.S student of medical-surgery nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 6, 7th Saadi Alley, Old Terminal, Yasuj, Iran.

City
Yasuj

Province
Kohgiluyeh-va-Boyerahmad

Postal code
7591974433

Phone
+98 74 3322 1350

Email
t60.taheri@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Tahereh Taheri

Position
M.S student of medical-surgical nursing

Latest degree
Bachelor

Other areas of specialty/work
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No. 6, 7th Saadi Alley, Old Terminal, Yasuj, Iran.

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Province
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Postal code
7591974433

Phone
+98 74 3322 1350

Email
t60.taheri@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Tahereh Taheri

Position
M.S student of medical-surgical nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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No. 6, 7th Saadi Alley, Old Terminal, Yasuj

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Yasuj

Province
Kohgiluyeh-va-Boyerahmad

Postal code
7591974433

Phone
+98 74 3322 1350

Email
t60.taheri@gmail.com

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