Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Milk protein concentrate (MPC) supplementation on oxidative stress, immune function, quality of life and anthropometric measurements in patients with Acquired Immune Deficiency Syndrome; a double-blind randomized clinical trial

Protocol summary

Study aim

Determination and comparison of mean anthropometric indices, quality of life, renal indices (creatinine and BUN), oxidative stress (serum levels of total antioxidant capacity and general oxidative status), inflammatory ALB protein (serum ESR, hs-CRP level), immunity (CD8 and CD4) in patients with Acquired Immune Deficiency Syndrome (AIDS) and its comparison with the control group before and after the intervention

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, on 80 patients. The site is used for randomization. https://www.sealedenvelope.com/simple-randomiser/v1/lists

Settings and conduct

Patients are selected from Masih Daneshvari Hospital and questionnaires and anthropometric and biochemical tests are performed on them.Also, the sachets are the same in each group to be blinded.

Participants/Inclusion and exclusion criteria

CD4 levels should be less than 500 Patients with AIDS are fully approved. Only patients with AIDS who have passed three months of treatment Use of protein supplements Sensitivity to dairy products Do not take calcium supplements or any product containing it People in addition to AIDS, other diseases including, metabolic syndrome, diabetic foot ulcer, coronary artery disease, lung infection. Patients including severe renal, hepatic, thyroid and parathyroid, gastrointestinal and heart disease, and cancer

Intervention groups

Participants are placed in one of two intervention or placebo groups. Patients will be divided into two groups based on random allocation. The first group of patients who receive Pegah MPC powder (condensed milk powder) at the rate of 25 grams per day and the second group of AIDS patients are homogeneous in terms of age and sex who will be selected as a control.

Main outcome variables

Anthropometrics, Quality of life, Inflammatory, Immune, Renal, Protein, Oxidative stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150909023957N9**
Registration date: **2021-06-20, 1400/03/30**
Registration timing: **prospective**

Last update: **2021-06-20, 1400/03/30**
Update count: **0**

Registration date

2021-06-20, 1400/03/30

Registrant information

Name
Sayyed Morteza Safavi

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 3792 3168

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01
Expected recruitment end date
2021-11-22, 1400/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Milk protein concentrate (MPC) supplementation on oxidative stress, immune function, quality of life and anthropometric measurements in patients with Acquired Immune Deficiency Syndrome; a double-blind randomized clinical trial

Public title
effect of milk protein concentrate in AIDS
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to cooperate with the project- CD4 level less than 500 - Patients with AIDS whose type of disease is fully confirmed through a complete medical examination and laboratory. Only patients with AIDS who have been on antiviral therapy for three months and are also on a consistent medication regimen should be included in this study.
Exclusion criteria:
Use of protein supplements Drug useAlcohol, acetylcysteine, NSAIDs three months before the study Sensitivity to dairy products Do not take calcium supplements or any product containing it Drugs or supplements that affect the immune and inflammatory systems, such as antioxidants, sexing, omega 3, curcumin People who, in addition to AIDS, suffer from other diseases that have oxidative stress as their etiology. Including: metabolic syndrome, diabetic foot ulcer, coronary artery disease, lung infection. Patients with clinical conditions that pose a serious health risk, including severe kidney, liver, thyroid and parathyroid disease, gastrointestinal and heart disease and cancer
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 80 people were identified based on the sample size formula and after matching age and gender (with a 5-year interval) and will be randomly divided into two groups. Randomization will be done by PBR method. Using a reputable website to generate random numbers: https://www.sealedenvelope.com/simple-randomiser/v1/lists It will be done in a randomized block method and participants will be placed in one of two intervention groups or placebo. Patients will be divided into two groups based on random allocation
Blinding (investigator's opinion)
Double blinded
Blinding description
Both the placebo and supplement groups receive the same sachets in appearance and size that are inseparable except for the barcode.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Vice-Chancellor in Research Affairs -Medical University of Isfahan
Street address
medical university of esfahan-hezarjerrib st
City
esfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2021-05-26, 1400/03/05
Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.079

Health conditions studied

1

Description of health condition studied
HIV,AIDS
ICD-10 code
B20
ICD-10 code description
Human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description
Anthropometric evaluation

Timepoint
Beginning and end of the study
Method of measurement
Using tape measure and scales

2

Description
Evaluation of safety indicators
Timepoint
Beginning and end of the study
Method of measurement
CD4, CD8 by flow cytometry.

3

Description
Evaluation of oxidative stress indices
Timepoint
Beginning and end of the study
Method of measurement
Evaluation of serum level of total antioxidant capacity (TAC) and total oxidative capacity (TOC) by Kiazist diagnostic kits

4

Description
Evaluation of inflammatory indicators
Timepoint
Beginning and end of the study
Method of measurement
The inflammatory marker ESR is determined by sodium citrate anticoagulant and CRP by ELISA and commercial German LDN kit.

5

Description
Quality of Life
Timepoint
Beginning and end of the study
Method of measurement
Quality of Life Questionnaire through HIV Disability Questionnaire (HDQ)

Secondary outcomes

1

Description
Evaluation of renal index
Timepoint
Beginning and end of the study
Method of measurement
Creatine test and BUN test are performed based on enzymatic method.

2

Description
Evaluation of protein index
Timepoint
Beginning and end of the study
Method of measurement
Albumin levels are measured based on the Bromocresol Green test

Intervention groups

1

Description
Intervention group: Powder (condensed milk powder) MPC will receive 25 grams per day for 8 weeks
Category
Other

2

Description
Control group: They will receive 25 grams of Malto Dextrin sachet for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih daneshvari hospital
Full name of responsible person
Payam Tabarsi
Street address
Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran
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pr.nritld@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Morteza Safavi
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Hezar Jarib Avenue, Isfahan University of Medical Sciences, School of Nutrition and Food Science, Isfahan
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safavimorteza@nutr.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
55
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

2

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Payam Tabarsi
Street address
Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran
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Postal code
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Phone
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Email
pr.nritld@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
45
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
payam tabarsi
Position
professor
Latest degree
Subspecialist
Other areas of specialty/work
Infectious diseases
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Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Sayyed Morteza Safavi
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
In the case of data dissemination, it can be shared after identifying individuals, in the case of the study protocol, there is a decision to publish it before the articles are published, and a clinical study report will be published.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
For researchers working in universities and industrial research centers
Under which criteria data/document could be used
The data will be delivered but their analysis or dissemination will no longer be allowed.
From where data/document is obtainable
mohammad ali hojjati kermaniv,masih daneshvari hospital ,tehran,iran
What processes are involved for a request to access data/document
After receiving the request and review, the documents will be sent within 2 weeks if approved.
Comments