ISRCTN49673328 https://doi.org/10.1186/ISRCTN49673328

The effects of IMMUTONIC capsule oral three times daily for 1 week on volunteers with flu symptoms, their blood immune parameters and CD4 T-cells

Submission date
17/07/2020

Recruitment status
No longer recruiting

Registration date
29/12/2020

Overall study status
Completed

Last Edited
29/12/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many herbs and natural foods have been historically recognized as having an effective anti-inflammatory response and promoting a healthy immune response as well as having antibacterial and antiviral effects. The clinical use of some medications can cause serious side effects. The researchers propose that natural ingredients could serve as a better treatment approach. This study aims to evaluate the effect of IMMUTONIC capsules in human volunteers with flu symptoms.

Who can participate?
Men and women aged between 21 and 60 with flu symptoms

What does the study involve?
Volunteers take IMMUTONIC capsule three times daily after meals for 1 week. Flu symptoms are assessed after 3 days and 7 days. Blood samples are taken before and after taking the IMMUTONIC capsule.

What are the possible benefits and risks of participating?
The possible benefits include improved health and boosted immunity. There are no risks of participating.

Where is the study run from?
Yemen University (Yemen)

When is the study starting and how long is it expected to run for?
February 2020 to July 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Dr Hussien O. Kadi
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Contact information

Type(s)
Scientific

Contact name
Prof Hussien Kadi

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effects of IMMUTONIC capsule oral three times daily for 1 week on volunteers with influenza symptoms, their blood immune parameters and CD4 T-lymphocytes: a randomized clinical trial

Study objectives
The hypothesis of new formulation of IMMUTONIC capsule contain mixture of six natural food materials/ingredients with different amounts for each one which was done by Prof. Dr. Hussien O. Kadi (Patent).

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 15/3/2020, Ethics Committee of Yemen University, Faculty of Medical Sciences (60 St. Yemen University, Faculty of Medical Sciences, Sana'a, Yemen; +967 (0)771211157, alahamdi.yem@gmail.com), ref: 12020

Study design
Randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Influenza symptoms

Interventions
Twenty-four male and female adult volunteers, aged between 21 and 60 years are selected for the study. The volunteers are free from significant cardiac, hepatic, renal, pulmonary, gastrointestinal, neurological or hematological disease as determined by way of medical histories, physical examinations. Volunteers take an IMMUTONIC capsule three times daily after meals for 1 week. Flu symptoms are measured at follow up after 3 days and 7 days using improving health scale 0-5.

Intervention Type
Supplement

Primary outcome measure
Flu symptoms assessed using improving health scale (0-5) before and 3 and 7 days after treatment

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/02/2020

Completion date

15/07/2020

Eligibility

Key inclusion criteria
1. Male and female adult volunteers, aged between 21 and 60 years, with flu symptoms
2. Free from significant cardiac, hepatic, renal, pulmonary, gastrointestinal, neurological or hematological disease as determined by way of medical histories, physical examinations

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Total final enrolment
49

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/2020

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
Yemen

Study participating centre
Yemen University
Faculty of Medical Sciences
Sana'a
Yemen
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Sponsor information

Organisation
Yemen University

Sponsor details
60 St.
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Sponsor type
University/education

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results have been published (see publications list).

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication and are available from Prof. Dr Hussien O. Kadi (hussien62@yahoo.com).

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/06/2020	20/07/2020	Yes	No