

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	<input type="checkbox"/> Prospectively registered
Registration date 29/12/2020	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/12/2020	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
hussien62@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Prof Hussien Kadi

ORCID ID
<https://orcid.org/0000-0002-2316-9429>

Contact details
Yemen University
Sana'a
Yemen
-
+967 (0)711114951
hussien62@yahoo.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes