

# 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

<b>Submission date</b> 17/07/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/12/2020	<b>Condition category</b> 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

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## Additional identifiers

## 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?
<a href="#">Results article</a>	results	30/06/2020	20/07/2020	Yes	No