

# Efficacy of curcumin as adjuvant therapy to improve remission in myeloma patients

<b>Submission date</b> 31/10/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/11/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/12/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Multiple myeloma is a clonal plasma cell malignancy that accounts for slightly more than 10% of all hematologic cancers. The therapy varies from chemotherapy, autologous bone marrow transplant, to novel agents. Chemotherapy for myeloma with Melphalan and prednisone produces an objective response in 50–60% of patients.

Curcumin is a natural polyphenol compound derived from turmeric (*Curcuma longa*). A number of preclinical studies have demonstrated that curcumin has anticancer effects against a variety of tumors, myeloma, both in vitro and in vivo. The safety of curcumin has been approved by the Food and Drug Administration and World Health Organization; In addition, its safety is strongly supported by the fact that this agent has been used in traditional Indonesia, India and Chinese medicine

The primary outcome of this study was to prove the efficacy of curcumin in the improvement of the remission status in myeloma patient. The secondary outcome was to evaluate the effect of curcumin to various disease activity, including NF- $\kappa$ B, IL-6, VEGF, TNF- $\alpha$ , CRP, and LDH.

### Who can participate?

Multiple myeloma patients aged over 18 years who are ineligible for transplant

### What does the study involve?

Patients will be randomly allocated to receive chemotherapy alone or chemotherapy plus curcumin for four 28 day cycles.

### What are the possible benefits and risks of participating?

If the administration of curcumin can improve remission in the sample population, it certainly can be proposed as a useful complementary therapy

### Where is the study run from?

Dr Kariadi General Hospital, Indonesia

### When is the study starting and how long is it expected to run for?

February 2016 to February 2017

Who is funding the study?  
LPDP (Lembaga Pengelola Dana Pendidikan), Indonesia

Who is the main contact?  
Dr Damai Santosa  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
3000113510022

## Study information

**Scientific Title**  
The effect of curcumin on remission status and survival on myeloma patients treated with melphalan prednisone: a pilot randomized clinical trial

**Study objectives**

1. The addition of curcumin to treatment will increase overall remission in myeloma patients treated with melphalan prednisone
2. The addition of curcumin to treatment will decrease measures of NF- $\kappa$ B, IL-6, VEGF, TNF- $\alpha$ , CRP, and LDH in myeloma patients treated with melphalan prednisone

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 17/02/2016, Komisi Etik Penelitian Kesehatan (Jl. Dr. Soetomo No18, Semarang City, Central Java Province, Indonesia, 50244; +62243818550), ref: 16/EC/FK-RSDK/I/2016

**Study design**

Interventional randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

See additional files (in Indonesian)

**Health condition(s) or problem(s) studied**

Multiple myeloma

**Interventions**

Patients were allocated randomly in two parallel study groups using a sealed envelope method. The treatment group (17 patients) was treated with MP regimen (melphalan 4mg/m<sup>2</sup>, prednisone 40mg/m<sup>2</sup>, for 7 days) and curcumin 8 grams/daily for 28 days. The control group (16 patients) was treated with MP regimen and placebo. All of the patients were evaluated every 28 days for a total of 4 cycles treatment.

Each patient was followed up every 28 days, for 4 cycles. A checklist was used for data collection and filled in each visit separately. The contents of checklist were the patients' profiles (age, sex, education level), and laboratory data, including full blood count (FBC), urea, creatinine, NF- $\kappa$ B, IL-6, CRP, LDH, VEGF, and patient group (treatment or control). The physical exam of the patients was performed by a physician every visit (single blindness). Remission and TNF- $\alpha$  was evaluated after the end of study

**Intervention Type**

Supplement

**Primary outcome measure**

Overall remission at the end of the study period

**Secondary outcome measures**

Levels of NF-kB, TNF-a, VEGF, IL-6, CRP, LDH measured using blood test every 28 days throughout the study period

**Overall study start date**

29/09/2015

**Completion date**

30/06/2017

**Eligibility****Key inclusion criteria**

1. New multiple myeloma patients
2. Aged over 18 years old
3. Ineligible for transplant

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

20 participants, 10 in each group

**Total final enrolment**

33

**Key exclusion criteria**

1. Sepsis
2. Severe infection
3. Pregnancy
4. Patients with severe disease (such as acute hepatitis, chronic hepatitis, cirrhosis)
5. Elevation of aspartate aminotransferase (AST) >3 times upper limit normal (ULN)
6. Participated in another study
7. Poor performance status

**Date of first enrolment**

01/02/2016

**Date of final enrolment**

01/05/2017

## **Locations**

**Countries of recruitment**

Indonesia

**Study participating centre**

**dr. Kariadi General Hospital**

Jl. Dr. Sutomo no 16

Semarang

Indonesia

3374010

## **Sponsor information**

**Organisation**

LPDP (Lembaga Pengelola Dana Pendidikan)

**Sponsor details**

Ministry of Finance of Republic of Indonesia

dr. Wahidin Raya Street No1

Jakarta

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10710

+6221-3500842

tesisdisertasi.lpd@kemenkeu.go.id

**Sponsor type**

Government

**Website**

<http://www.lpd.kemenkeu.go.id/program/pengelolaan-dana/#>

**ROR**

<https://ror.org/04wvvj212>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Lembaga Pengelola Dana Pendidikan (LPDP)

## Results and Publications

**Publication and dissemination plan**

Thesis defence in Faculty of Medicine, Diponegoro University, March 2018

**Intention to publish date**

03/03/2018

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. please contact Ms Haidi/Kiki, email address; hemasemarang@gmail.com, type of data=excel, the data will become available for 10 years, the access criteria data will be shared including with hematologist that interesting in myeloma research, the types of analyses dependent on their study purpose, and the mechanism; please send email to us with the study protocol and we will discuss to our ethical committee

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/04/2022	30/12/2022	Yes	No