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

Submission date
31/10/2019

Recruitment status
No longer recruiting

Registration date
08/11/2019

Overall study status
Completed

Last Edited
30/12/2022

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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-κB, IL-6, VEGF, TNF-α, 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?
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Contact information

Type(s)
Scientific

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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-κB, IL-6, VEGF, TNF-α, 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^2, prednisone 40mg/m^2, 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-kB, 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-a 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
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Indonesia
3374010

Sponsor information

Organisation
LPDP (Lembaga Pengelola Dana Pendidikan)

Sponsor details
Ministry of Finance of Republic of Indonesia
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10710
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tesisdisertasi.lpdp@kemenkeu.go.id

Sponsor type
Government

Website
http://www.lpdp.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?
Results article		01/04/2022	30/12/2022	Yes	No