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Zerumbone, a compound extracted from bitter ginger (Zingiber zerumbet), for patients with solid tumors with no treatment options: A pilot clinical study

Submission date
03/07/2023

Recruitment status
No longer recruiting

Registration date
06/07/2023

Overall study status
Completed

Last Edited
08/03/2024

Condition category
Cancer

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

Plain English summary of protocol
Background and study aims
This research study aims to explore the potential benefits of using bitter ginger, specifically a natural compound called zerumbone found in bitter ginger plants (Zingiber zerumbet), in cancer patients who have limited treatment options. Bitter ginger has been found to possess several properties, such as anti-inflammatory, antioxidant, and analgesic effects. The study aims to assess whether bitter ginger can improve the quality of life and symptom control in these patients.

Who can participate?
Adult patients over the age of 18 years with advanced solid tumors who have exhausted their treatment options are eligible to participate in this study. The study included both male and female patients with various types of cancers.

What does the study involve?
This pilot study was conducted at a single center and involved a total of 35 patients. Participants were given 400 mg of zerumbone, derived from bitter ginger, twice a day for a duration of eight weeks. The patients visited the clinic for three appointments during the study period, where they underwent clinical examinations, and blood tests, and completed specific questionnaires to assess their quality of life, anxiety, depression, fatigue, and sleep quality. Adverse events were also monitored.

What are the possible benefits and risks of participating?
The study is expected to show promising results in improving the quality of life of patients, particularly in the emotional, social, and activity dimensions. Patients may experience improvements in anxiety, depression, and fatigue. Bitter ginger is generally well-tolerated, with only a few mild side effects expected. However, it is important to note that this is a pilot study with a small number of participants and further research with a larger sample size and a control group is needed to confirm these preliminary findings.

Where is the study run from?
The study was conducted at the clinical oncology outpatient clinics of Anchieta Hospital in São Bernardo do Campo and Mario Covas State Hospital in Santo André, both in São Paulo, Brazil. It was affiliated with the ABC Foundation School of Medicine.

When did the study start and how long is it expected to run for?
June 2018 to February 2023

Who is funding the study?
The study was funded through a partnership between the ABC School of Medicine, the National Institute for Research in the Amazon (Instituto Nacional de Pesquisas da Amazônia - INPA), and the Biozer Laboratory.

Who is the main contact?
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Study information

Scientific Title
Bitter ginger (Zingiber zerumbet) for patients with advanced cancer: A pilot clinical study

Study objectives
Zerumbone is a natural compound found in bitter ginger plants (Zingiber zerumbet) that shows antiproliferative, antioxidant, anti-inflammatory, and analgesic properties. This study aims to investigate the role of zerumbone in improving the quality of life and symptom control in cancer patients with no treatment options

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/08/2018, ABC Foundation School of Medicine (Faculdade de Medicina da Fundação ABC; FMABC) (Avenida Príncipe de Gales 821, Santo André, 09060-650, Brazil; +55114993-5453; cep@fmabc.br), ref: 93459418.1.0000.0082

Primary study design
Interventional

Study design
Phase II pilot study

Study type(s)
Quality of life, Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Patients with advanced solid tumors without any more specific anti-neoplastic treatment options

Interventions
In this pilot study, patients were recruited from clinical oncology outpatient clinics in São Bernardo do Campo and Santo André, São Paulo, Brazil. Zingiber zerumbet (ZZ) rhizomes were collected from Manaus, Amazonas, Brazil, and processed to obtain crude and hydroalcoholic

extracts. The extracts were analyzed using thin-layer chromatography (TLC) and high-performance liquid chromatography (HPLC) to identify their components. The Zingiber zerumbet rhizome extract was encapsulated in 400 mg gelatin capsules and given to participants to be administered twice a day for eight weeks. Adherence to the treatment was monitored by evaluating the returning medication packages. The protocol involved three visits: the first visit (T = 0) before initiating the treatment, followed by two other visits every four weeks until week eight of treatment. At each visit, the patients underwent anamnesis, clinical examination, blood collection, and specific questionnaire assessments.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Bitter ginger (Zingiber zerumbet)

Primary outcome(s)
Quality of life measured using the EORTC Core Quality of Life questionnaire (EORTC QLQ-C30) at T=0 (before starting the medication), Week 4 and Week 8

Key secondary outcome(s)
Fatigue measured using Functional Assessment of Chronic Illness Therapy Fatigue (FACIT F) scale at T=0 (before starting the medication), Week 4 and Week 8

Completion date
01/02/2023

Eligibility

Key inclusion criteria
1. Aged over 18 years old, regardless of sex,
2. Previously treated advanced solid tumors with no treatment options according to the attending physician
3. Life expectancy of at least two months
4. Creatine levels up to twice the upper limit of normal (ULN)
5. Serum glutamic oxaloacetic transaminase (SGOT) and glutamic pyruvic transaminase (GPT) levels up to twice the ULN (for patients with liver disease, levels up to 2.5 times the ULN are considered), and direct bilirubin (DB) levels up to 1.5 times the ULN (for patients with liver disease, levels up to 2.5 times the ULN are considered).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
16

Key exclusion criteria
1. Objections to the procedures in the study or the terms described in the informed consent form
2. Pregnancy and/or lactation (female patients of childbearing age had to present a negative quantitative blood human chorionic gonadotropin
[HCG] test)
3. Current treatment with chemotherapeutic or other antineoplastic agents for antitumor therapy
4. Analgesic radiotherapy and zoledronic acid administration for bone metastases were accepted as supportive therapies
5. Patients with a diagnosis of renal failure or severe liver disease
6. A history of hypersensitivity to formula components
7. Emotional disorders that could compromise data collection

Date of first enrolment
01/10/2018

Date of final enrolment
01/11/2022

Locations

Countries of recruitment
Brazil

Study participating centre
Faculdade de Medicina da Fundação ABC (FMABC)
Avenida Principe de Gales 821, Santo Andre, Brasil
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Sponsor information

Organisation
Biozer da Amazônia

Funder(s)

Funder type
Industry

Funder Name
Biozer da Amazônia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Auro del Giglio, aurodelgiglio@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/01/2024	08/03/2024	Yes	No