Trial registered on ANZCTR

Trial ID
ACTRN12616000028404
Ethics application status
Approved
Date submitted
17/12/2015
Date registered
18/01/2016
Type of registration
Prospectively registered

Titles & IDs

Public title
The efficacy of adjunctive Garcinia mangostana linn (mangosteen) pericarp for bipolar depression: A 24-week double-blind, randomised, placebo controlled trial.
Scientific title
The efficacy of adjunctive Garcinia mangostana linn (mangosteen) pericarp for bipolar depression: A 24-week double-blind, randomised, placebo controlled trial.
Secondary ID [1]
Nil Known
Universal Trial Number (UTN)
Trial acronym
MANGO BD

Health condition

Health condition(s) or problem(s) studied:
Bipolar depression
Condition category
Condition code
Mental Health
Depression
Mental Health
Other mental health disorders

Intervention/exposure

Study type
Interventional
Description of intervention(s) / exposure

1000mg/day of oral (2 capsules, once a day) of adjunctive Garcinia Mangostana Linn. (mangosteen) perica rp will be trialled against placebo for 24 weeks to determine the efficacy of mangosteen pericarp for the tre atment of bipolar depression. Adherence will be monitored by participants returning all bottles of investiga tional product, including any unused capsules.

Intervention code [1]

Treatment: Drugs

Comparator / control treatment

Placebo (inactive starch)

Control group

Placebo

Outcomes

Primary outcome [1]

change in severity of mood symptoms, measured using the Montgomery Asberg Depression Rating Scale (MADRS)

Timepoint [1]

Conducted at all trial visits - Baseline (week 0) and every four weeks after that (week 4, 8, 12, 16, 20, 24)

Secondary outcome [1]

Change in Clinical Global Impressions - Improvement Scale (CGI-I)

Timepoint [1]

Conducted at all trial visits - Baseline (week 0), every four weeks after that (week 4, 8, 12, 16, 20, 24) and week 28 (4 weeks post discontinuation).

Secondary outcome [2]

Change in Clincial Global Impressions - Severity Scale (CGI-S)

Timepoint [2]

Conducted at all trial visits - Baseline (week 0), every four weeks after that (week 4, 8, 12, 16, 20, 24) and week 28 (4 weeks post discontinuation).

Secondary outcome [3]

Change in anxiety symptoms based on the Hamilton Anxeity Rating Scale (HAM-A)

Timepoint [3]

Conducted at all trial visits - Baseline (week 0), every four weeks after that (week 4, 8, 12, 16, 20, 24) and week 28 (4 weeks post discontinuation).

Secondary outcome [4]

Change in bipolar symptomology as measured by Bipolar Depression Rating Scale (BDRS)

Timepoint [4]

Conducted at all trial visits - Baseline (week 0), every four weeks after that (week 4, 8, 12, 16, 20, 24) and week 28 (4 weeks post discontinuation).

Secondary outcome [5]

Change in mania symptomology measured by the Young Mania Rating Scale (YMRS)

Timepoint [5]

Conducted at all trial visits - Baseline (week 0), every four weeks after that (week 4, 8, 12, 16, 20, 24) and four weeks post-discontinuation at week 28

Secondary outcome [6]

Change in Patient Global Impression Scale (PGI)

Timepoint [6]

Conducted every four weeks after baseline (week 4, 8, 12, 16, 20, 24) and week 28 (4 weeks post discontin uation).

Secondary outcome [7]

Change in quality of life measured by Quality of life Enjoyment and Stisfaction Questionnaire - Short For m (Q-LES-Q-SF)

Timepoint [7]

Conducted at all trial visits - Baseline (week 0), every four weeks after that (week 4, 8, 12, 16, 20, 24) and week 28 (4 weeks post discontinuation).

Secondary outcome [8]

Change in Functioning measured by Social Occupational Functioning Scale (SOFAS)

Timepoint [8]

Conducted at all trial visits - Baseline (week 0), every four weeks after that (week 4, 8, 12, 16, 20, 24) and week 28 (4 weeks post discontinuation).

Secondary outcome [9]

Change in Functioning measured by Range of Impaired Functioning Tool (LIFE-RIFT)

Timepoint [9]

Conducted at all trial visits - Baseline (week 0), every four weeks after that (week 4, 8, 12, 16, 20, 24) and week 28 (4 weeks post discontinuation).

Secondary outcome [10]

Change in oxidative stress (malondialdehyde) markers

Timepoint [10]

Bloods collected from consenting participants at baseline, week 24 and week 28

Secondary outcome [11]

Changes in severity of mood symptoms following discontinuation of trial medication, measured using MA DRS

Timepoint [11]

The post-discontinuation of treatment (week 28) will be analysed both between week 24 and week 28.

Secondary outcome [12]

Change in inflamatory (IL-6, TNF-alpha and CRP) markers

Timepoint [12]

Bloods collected from consenting participants at baseline, week 24 and week 28

Secondary outcome [13]

Change in neuroprotection (Bcl-2) markers

Timepoint [13]

Bloods collected from consenting participants at baseline, week 24 and week 28

Eligibility

Key inclusion criteria

1. Must be required to meet DSM-5 criteria for bipolar disorderI or II, cyclothymic disorder or bipolar diso rder not elsewhere classified (NEC),

2. Have a current episode of depressive illness with a MADRS score greater than or equal to 20

3. Have capacity to consent to the study and comply with study procedures

4. Any form of therapy must be stable for the last month

5. Using effective contraception if female, sexually active and of child bearing potential

6. Be able to speak, read, write and understand the English language,

7. Participants will be required to nominate a current treating physician and will not be eligible to enter the study until one is identified.

8. Have the capacity to consent to the study and comply with study procedures,

Minimum age

18 Years

Maximum age

No limit

Gender

Both males and females

Can healthy volunteers participate?

No

Key exclusion criteria

1. Participants with a known or suspected active systemic medical disorder,

2. Individuals who are pregnant or lactating (participants will be requested to conduct a urine pregnancy te st if sexually active and of child-bearing age),

3. Participants currently enrolled in any other intervention study will be excluded,

4. Individuals who are intolerant, allergic to or have had an anaphylactic reaction to any components of the preparation,

5. Inability to comply with either the requirements of informed consent or the treatment protocol.

Study design

Purpose of the study

Treatment

Allocation to intervention

Randomised controlled trial

Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)

An independent researcher utilising a block design will develop the computer-generated randomisation pla n. Trial clinicians will allocate packs sequentially, and bottles are identical so as to conceal treatment alloc ation and blinding. To facilitate the double-blinding process, the trial medications will be dispensed by an i ndependent pharmacist in identical numbers and capsule forms in sealed containers.

Methods used to generate the sequence in which subjects will be randomised (sequence generation)

Permutated block randomisation utilising a block design on a computer-generated randomisation.

Masking / blinding

Blinded (masking used)

Who is / are masked / blinded?

The people receiving the treatment/s
The people administering the treatment/s
The people assessing the outcomes
The people analysing the results/data

Intervention assignment

Parallel

Other design features

Phase

Phase 2

Type of endpoint(s)

Efficacy

Recruitment

Anticipated date of first participant enrolment
1/02/2016
Actual date of first participant enrolment
Anticipated date last participant enrolled
31/01/2018
Actual date last participant enrolled
Anticipated date of last data collection
Actual date of last data collection
Target sample size
80
Actual sample size
Recruitment status
Not yet recruiting
Recruitment in Australia
Recruitment state(s)
VIC
Recruitment hospital [1]
The Melbourne Clinic - Richmond
Recruitment hospital [2]
Albert Road Clinic - Melbourne
Recruitment postcode(s) [1]
3121 - Richmond
Recruitment postcode(s) [2]
3004 - Melbourne

Funding & Sponsors

Funding source category [1]
University
Name [1]
Deakin University, IMPACT SRC Seed Funding Grant
Address [1]
IMPACT SRC
PO BOX 281
Geelong Victoria 3220
Country [1]
Australia
Primary sponsor type
Hospital
Name
Barwon Health
Address
Research Ethics, Governance and Integrity (REGI) Unit
PO BOX 281
Geelong Victoria 3220
Country
Australia
Secondary sponsor category [1]
None
Name [1]
Address [1]
Country [1]

Other collaborator category [1]
University
Name [1]
University of Melbourne
Address [1]
The University of Melbourne
Victoria 3010
Country [1]
Australia

Ethics approval

Ethics application status
Approved
Ethics committee name [1]
Barwon Health Human Research Ethics Committee
Ethics committee address [1]
Research Ethics, Governance and Integrity (REGI) Unit
PO BOX 281
Geelong Victoria 3220
Ethics committee country [1]
Australia
Date submitted for ethics approval [1]
26/08/2015
Approval date [1]
18/11/2015
Ethics approval number [1]
Ethics committee name [2]
The Melbourne Clinic Research Ethics Committee
Ethics committee address [2]
130 Church St
RICHMOND, VIC 3121
Ethics committee country [2]
Australia
Date submitted for ethics approval [2]
31/07/2015
Approval date [2]
26/08/2015
Ethics approval number [2]
Ethics committee name [3]
Deakin University Human Research Ethics Committee
Ethics committee address [3]
Burwood Campus
Postal: 221 Burwood Highway
Burwood Victoria 3125
Ethics committee country [3]
Australia
Date submitted for ethics approval [3]
02/12/2015
Approval date [3]
16/12/2015
Ethics approval number [3]

Summary

Brief summary

Aims

The primary aim of this study is to investigate the efficacy of adjunctive mangosteen pericarp 1000mg/day for the treatment of bipolar depression using a 24 Week randomised, placebo controlled trial. The primary outcome measure will be the change in severity of mood symptoms, measured using the Montgomery Asb erg Depression Rating Scale (MADRS). Secondary outcomes include global psychopathology, substance u se, functioning, quality of life, and safety and tolerability data. A follow-up interview will be conducted 4 weeks posttreatment to determine any outcomes following cessation of the trial agent.

Method

We plan to recruit a total of 80 participants aged 18+years with moderate to severe bipolar depression (hav ing a DSM5 diagnosis of bipolar I or II, cyclothymic disorder or bipolar disorder not elsewhere classified (NEC), determined using the Structured Clinical Interview for DSM Disorders 5 (SCID5) and meeting crite ria of a Montgomery Asberg Depression Rating Scale (MADRS) score of greater than or equal to 20.

Participants will attend a screening visit to ascertain suitability and once randomized they will receive a m onth's supply of either 1000mg/day of mangosteen or matched placebo to be taken in addition to their treat ment as usual. Participants take two capsules per day.

Participants will visit the study site at weeks 4, 8, 12, 16, 20 24 and 28 (4 weeks posttreatment discontinuat ion) where a battery of validated outcome measures will be administered by trained research staff. Particip ants will be asked to discuss their symptoms, side effects and any issues the participant would like to raise regarding the trial. Participants will be notified of which arm of the study they took part in and a summary of results at the completion of the study.

Trial website

Trial related presentations / publications

Public notes

Contacts

Principal investigator

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