ISRCTN42589932 https://doi.org/10.1186/ISRCTN42589932

The beneficial effect on mood of a food supplement based on S-adenosyl methionine and probiotics

Submission date
03/08/2021

Recruitment status
No longer recruiting

Registration date
04/08/2021

Overall study status
Completed

Last Edited
22/04/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Subthreshold depression (SD) is defined by the presence of two or more depressive symptoms for 2 weeks and does not meet the criteria for diagnosis of major depressive disorder (MDD) and /or dysthymia (a milder but long-lasting form of depression), although it may have a significant impact on the quality of life.
S-adenosylmethionine (SAMe) has a significant mood-enhancing potential. Its effectiveness as an antidepressant has been shown by a number of clinical studies where it was used alone to combat mild to moderate depressive symptoms or in combination with traditional antidepressant medications in a moderate to severe course of disease. Differently from the other antidepressant drugs, SAMe is not associated with sexual and cognitive/memory dysfunction. In the light of available evidence, it is best to use SAMe in patients with mild to moderate depression, rather rely on conventional antidepressant medicines, which may increase the risk of toxicity in such patients.
Probiotics are health-promoting live microorganisms and are used to balance gut dysbiosis (bacteria imbalance), which may be associated with several intestinal and extraintestinal disorders. Certain probiotic species have been proved in clinical studies to have considerable antidepressant effects. The aim of this study is to find out whether supplementation with SAMe and probiotics is an effective treatment for depressive symptoms in patients with SD.

Who can participate?
People aged 18-65 years with altered mood

What does the study involve?
Participants are randomly allocated into two groups to take either a food supplement containing SAMe and probiotics or a placebo (dummy) supplement daily for 3 months. After a 1-month wash-out period where no treatment will be given participants switch groups for a further 3 months of treatment.

What are the possible benefits and risks of participating?
Participants may benefit from improved mood and will be continuously monitored about their health.

Where is the study run from?
Medical Doctor's Office site in Caserta (Italy)

When is the study starting and how long is it expected to run for?
September 2020 to March 2022

Who is funding the study?
Truffini & Reggè Farmaceutici S.r.l. (Italy)

Who is the main contact?
Prof. Maria Daglia (scientific)
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Contact information

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Additional identifiers

Protocol serial number
SAME122

Study information

Scientific Title
Double-blind, randomized, parallel-group, monocentric, placebo-controlled cross-over clinical trial on the effect of a food supplement based on S-adenosyl methionine and probiotics to promote normal mood by reducing subthreshold depression as a risk factor for major depression

Acronym
SAMEP

Study objectives
The primary outcome is to evaluate the efficacy of the food supplement containing S-adenosylmethionine (SAMe) and probiotics for maintaining normal mood by reducing subthreshold depression as a risk factor for major depression. This assessment was measured by administering to recruited subjects the validated Patient Health Questionnaire-9 (PHQ-9) and Hamilton Depression Rating Scale (HAM-D).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/10/2020, ASL Caserta Campania Nord Ethics Committee (Via Unità Italiana, n28, 81100, Caserta, Italy; +39 (0)825203025; comitatoeticoav@agmail.it), ref: 1491 17/11/2020

Study design
Interventional monocentric randomized double-blind placebo-controlled cross-over clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Subthreshold depression

Interventions

Subjects will take the food supplement or placebo daily for 3 months, then a 1-month wash-out period is planned (no treatment will be administered). Subsequently, subjects assigned to the treated group will be reassigned to the control group and vice versa (a further 3 months of treatment), as a cross-over design.

The randomization sequence was generated by a statistician using STATA 16 software (Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC) and, the randomization list will be kept hidden. Subjects were assigned to each treatment group (food supplement or placebo) casually and by simple randomisation (1:1 allocation ratio). The randomization code will consist of a three-digit number as indicated in the respective Case Report Form (CRF).

In the clinical study 80 participants were enrolled and divided into two groups (40 for each group):
Group 1: daily intake of food supplement
Group 2: daily intake of placebo

Participants will undergo four visits (baseline = t0, after 12 weeks = t12, after 16 weeks (4 weeks of wash-out) = t16 and after 28 weeks = t28, in an outpatient setting. After each clinical visit, all data are filled in the CRF by physicians. In detail, the data acquired are:
Baseline visit (t0): signature of informed consent; information on the sociodemographic, clinical and symptomatologic
characteristics of the participants; PHQ-9 questionnaire; HAM-D questionnaire, urine analysis for the determination of cortisol and epinephrine.
After 12 weeks of treatment (t12): assessment of possible adverse reaction; PHQ-9 questionnaire; HAM-D questionnaire, urine analysis for the determination of cortisol and epinephrine.
After 16 weeks - t16 (4 weeks of wash-out)): PHQ-9 questionnaire; HAM-D questionnaire,
After 28 weeks of the other treatment (t28): assessment of possible adverse reaction; PHQ-9 questionnaire; HAM-D questionnaire, urine analysis for the determination of cortisol and epinephrine.

Intervention Type
Supplement

Primary outcome(s)
Subthreshold depression as a risk factor for major depression, measured by the Patient Health Questionnaire-9 (PHQ-9) and Hamilton Depression Rating Scale (HAMD21) at t0, t12, t16 and t28

Key secondary outcome(s))
Urinary cortisol and epinephrine concentration assessed by urine analysis at t0, t12 and t28

Completion date
20/03/2022

Eligibility

Key inclusion criteria
1. Male and female in the age range 18 to 65 years
2. Subjects who present with altered mood tone
3. Subjects not eligible for antidepressant drugs
4. Subjects capable of understanding and complying with the requirements of the protocol

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Subjects with major depression remission or who have suffered from major depression in recent years
2. Individuals who have taken products, drugs or dietary supplements with psychological function activities in the 12 weeks prior to recruitment
3. Subjects suffering from diseases involving the cardiovascular, hepatic, renal, respiratory, nervous or lymphatic system
4. Subjects suffering from hypothyroidism
5. Pregnant women and those who have taken monoamine oxidase inhibitors in the 14 days prior to the recruitment

Date of first enrolment
05/08/2021

Date of final enrolment
20/08/2021

Locations

Countries of recruitment
Italy

Study participating centre
Medical Doctor's Office
Via Tommaso Picazio, 26 81100
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81100

Sponsor information

Organisation
Truffini & Reggè Farmaceutici S.r.l.

Funder(s)

Funder type
Industry

Funder Name
Truffini & Reggè Farmaceutici S.r.l.

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 Dr Agostino Greco (agostino.greco@alice.it).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/10/2022	19/04/2024	Yes	No
Participant information sheet			04/08/2021	No	Yes
Protocol file			04/08/2021	No	No