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A clinical study to assess the efficacy of a probiotic supplement for women to reduce depression and anxiety symptoms after giving birth

Submission date
22/11/2021

Recruitment status
No longer recruiting

Registration date
24/11/2021

Overall study status
Completed

Last Edited
17/01/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The existence of communication between the brain and the gut, known as the Gut-Brain axis, has for long been recognized. Consequently, the importance of maintaining a healthy microbiota (microorganisms including bacteria that live in the digestive tract) community in the regulation of the gut-brain axis is of paramount importance. Probiotic supplementation has been suggested to maintain, through gut microbiota modulation, the physiological state of the mental and physical well-being. In this context the use of probiotics could be of support to new-mothers to reduce the possibility of the onset of anxiety or stress after childbirth.

Who can participate?
Pregnant healthy women with no clinical history of depression.

What does the study involve?
The study involves the administration of two different food supplements for 90 days after giving birth: one with probiotics + vitamins and the other with vitamins only.

What are the possible benefits and risks of participating?
Risks associated with the intake of the product are considered from low to very low. Benefits associated with product use are amelioration of symptoms of depression and anxiety, of incidence of mastitis episodes, and of crying episodes of the child.

Where is the study run from?
Humanitas San Pio X Hospital (Italy)

When is the study starting and how long is it expected to run for?
September 2020 to July 2021

Who is funding the study?
Roelmi HPC (Italy)

Who is the main contact?
Dr Franco Vicariotto, ginecologia@vicariotto.com

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
K.E.HU.NN.NGN00.000.00.00_2019/FV

Study information

Scientific Title
A randomized double blind controlled clinical study to assess the effect of treatment with a probiotic supplement targeted to women after pregnancy, to reduce postpartum symptoms of depression and anxiety

Study objectives
The probiotic supplement is able to re-establish the microbial homeostasis in the gut and might positively influence the neural activity, resulting in the incidence reduction of depression or anxiety symptoms and post-natal stress.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 13/11/2019, Independent Ethics Committee for Non-Pharmacological Clinical Investigations (Via XX Settembre 30/4, 16121 Genova - Italy; +39 105454842; ssinf@messaggipec.it), ref: 2019/12

Study design
Multicenter randomized double-blind controlled clinical study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Improvement of post-partum depression and mastitis in healthy new mothers and reduction of excessive crying in the newborns.

Interventions
2 groups of 100 subjects were invited to orally take one capsule/day for 90 days, starting from delivery, as follows: one group (A) used the complete active treatment (Probiotics mix + multivitamin food supplement), one group (B) used the reference treatment (multivitamin food supplement). A restricted randomization list is generated by the site Study Coordinator using an appropriate statistic algorithm (“Wey’s urn”).

Intervention Type
Supplement

Primary outcome measure
Depression and anxiety symptoms and post-natal stress measured using the Edinburgh Postnatal Depression Scale (EPDS) after 45 and 90 days

Secondary outcome measures
1. Baby's crying, measured using Breastfeeding Self Efficacy Scale Short Form and Children Cry Questionnaires after 45 and 90 days.
2. Mastitis measured using Breastfeeding Quality Questionnaire after 45 and 90 days

Overall study start date
07/09/2019

Completion date
26/07/2021

Eligibility

Key inclusion criteria
Healthy pregnant female subjects after their delivery

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
200

Total final enrolment
200

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Subjects considered as not adequate to participate to the study by the investigator
3. Subjects with known or suspected sensitization to one or more test formulation ingredients
4. Adult protected by law (under control or hospitalized in public or private institutions for reasons other than research, or incarcerated)
5. Subjects not able to communicate or cooperate with the investigator for problems related to language, mental retardation or impaired brain function
6. Suffering from other psychiatric disorders such as schizophrenia, other psychotic disorders, bipolar disorder or substance use disorder
7. Serious physical illnesses or mental disorders due to a general medical condition which are judged by the investigator to render unsafe
8. A significant risk of infanticide according to the investigator assessment
9. Herbal remedies or psychotropic drugs that are intended for depression are taken within the last 2 weeks prior to baseline or during the study
10. Receiving counseling or psychological therapies at baseline or during the study
11. Participation in any clinical trial within the previous 3 months prior to baseline

Date of first enrolment
21/07/2020

Date of final enrolment
15/05/2021

Locations

Countries of recruitment

Italy

Study participating centre
Humanitas San Pio X Hospital
Via Francesco Nava, 31
Milan
Italy
20159

Study participating centre
San Giovanni Addolorata Hospital
Via dell'Amba Aradam, 9
Rome
Italy
00184

Study participating centre
Careggi University Hospital
Largo G. Alessandro Brambilla, 3
Flornce
Italy
50134

Study participating centre
Sant'Anna e San Sebastiano Hospital
Via Ferdinando Palasciano
Caserta
Italy
81100

Study participating centre
University Hospital
Viale Mario Bracci
Siena
Italy
53100

Study participating centre

University Hospital
Via Pozzuolo, 330
Udine
Italy
33100

Study participating centre
University Hospital
Piazza Luigi Miraglia, 2
Naples
Italy
80138

Study participating centre
A. Gemelli, University Hospital
Largo Agostino Gemelli, 8
Rome
Italy
00168

Study participating centre
S. Andrea University Hospital
Via di Grottarossa, 1035/1039
Rome
Italy
00189

Study participating centre
S. Pietro Fatebenefratelli Hospital
Via Cassia 600
Rome
Italy
00189

Sponsor information

Organisation
Roelmi HPC

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Sponsor type
Industry

Website
http://www.roelmihpc.com

Funder(s)

Funder type
Industry

Funder Name
RoelmiHPC

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/01/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/08/2023	17/01/2024	Yes	No