

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	<input type="checkbox"/> Prospectively registered
Registration date 24/11/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/01/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

Completion date

26/07/2021

Eligibility

Key inclusion criteria

Healthy pregnant female subjects after their delivery

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

Funder(s)

Funder type
Industry

Funder Name
RoelmiHPC

Results and Publications

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