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Live microbial feed supplements for male infertility

Submission date	Recruitment status	[_] Prospectively registered
19/08/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/09/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/07/2018	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
A couple's inability to conceive after 1 year of regular unprotected intercourse clinically defines infertility, a condition which affects approximately 15% of the reproductive-aged population. Over half of all cases are at least partly due to make fertility problems and up to 40% is due to male fertility problems alone. Male infertility is often linked to abnormalities apparent when the semen is examined. About one third of infertile men are affected by a condition called idiopathic (oligo)±(atheno)±(terato) spermia (iOAT): which occurs despite no evidence of any clinical, instrumental and biochemical sign. iOAT does not respond to therapy and affected men often require assistance if they are to reproduce. This study is investigating a new therapy for iOAT.

Who can participate?
Infertile men, aged 20-50 years with iOAT.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are given the drug Flortec-Bracco once a day for three months. Participants in group 2 are given a placebo (starch) tablet once a day for three months. Each participant provides two sperm samples before and then again after the treatment period. The samples are then analysed for sperm count and mobility (how well they move).

What are the possible benefits and risks of participating?
The only benefit for participating will be the fact that patients treated with the active drug might have their problem cured. No side effect s are expected.

Where is the study run from?
Gynepro Medical (Italy)

When is the study starting and how long is it expected to run for?
January 2015 to December 2016

Who is funding the study?
Gynepro Medical (Italy)

Who is the main contact?
Dr Carlo Maretti

Contact information

Type(s)
Public

Contact name
Dr Carlo Maretti

Contact details
via Somaglia 10
Piacenza
Italy
29121

Additional identifiers

Protocol serial number
2016/1

Study information

Scientific Title
Oral administration of a placebo (starch) or of an active drug (L. paracasei B21060 + arabinogalattan and fruttoligosaccarides (Flortec-Bracco)) to two distinct populations of (oligo)± (atheno)±(terato) spermic infertile patients. Comparison of efficacy and of safety between placebo and active drug for the treatment of (Oligo)±(atheno)±(terato) spermia associated to idiopathic male infertility.

Acronym
EPA (Evidence for Pregnancy Achievement)

Study objectives
The aim of this study is to assess whether oral administration of probiotics and prebiotics (L. paracasei B21060 + arabinogalattan and fruttoligosaccarides (Flortec-Bracco)) improves sperm count and fertility of dyspermic infertile patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics Committee, GynePro Medical, 29/06/2016, ref: CdB 0112016

Study design
Interventional double-blind placebo-controlled study

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Idiopathic (Oligo)±(atheno)±(terato) spermia associated to male infertility.

Interventions
This study consists of two arms. Participants will be randomly allocated to one of these arms.

The patients of the first arm will be treated with active drug: L. paracasei B21060 + arabinogalattan and fruttoligosaccarides (Flortec-Bracco) one medicine sachet (containing L. paracasei B21060≥ 5 x 109 Colony Forming Units, Arabinogalattan 1.243 g, fructo-oligosaccarides 700 mg, L-glutammin 500 mg) once a day for six months.

The patients of the second arm will assume one 1 g starch tablet once a day for three months.

Three months after the suspension of the therapies the patients of both arms will be submitted to sperm analysis, hormonal assessment and bilateral scrotal echographic scan. Medical events occurred in this time will be recorded as well.

Intervention Type
Supplement

Primary outcome(s)
Sperm concentration, sperm motility and percentage of typical sperm forms, measured at baseline and at 3 months

Key secondary outcome(s))
1. The number of biochemical pregnancies (detected by measuring serum β-hCG on at least two occasions 14 days after the last expected menstruation)
2. The numbers of clinical pregnancies (defined as detectable heart activity)

The differences between active drug or placebo group were assessed using the Mann–Whitney U test.

Completion date
01/12/2016

Eligibility

Key inclusion criteria
1. Infertile (oligo)±(atheno)±(terato) spermic infertile males aged 20-50
2. Normal sperm appearance, consistency, liquefaction, volume, and pH

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Azoospermia
2. Seminal white blood cell concentration greater than 1 million/ml and/or a positive seminal cultural analysis or 3. Positive urethral swab chlamydia test
4. Drug, tobacco, or alcohol abuse
5. Ongoing medical treatment
6. Previous cancer radiotherapy or chemotherapy
7. Palpable varicocele
8. X-ray exposure in the previous 8 months
9.Y chromosome microdeletion
10. Karyotype alterations
11. Presence of female factors for infertility
12. Female partner age > 35 years

Date of first enrolment
01/02/2015

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
Italy

Study participating centre
Gynepro Medical
via Tanquillo Cremona 8
Bologna
Italy
40137

Sponsor information

Organisation
Gynepro Medical

ROR
https://ror.org/03segdh23

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Gynepro Medical

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 Giorgio Cavallini

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes