

Live microbial feed supplements for male infertility

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

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 male 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 effects 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
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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 + arabinogalactan and fructooligosaccharides (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 + arabinogalactan and fructooligosaccharides (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

Primary study design

Interventional

Study design

Interventional double-blind placebo-controlled study

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 + arabinogalactan and fructooligosaccharides (Flortec-Bracco) one medicine sachet (containing L. paracasei B21060 $\geq 5 \times 10^9$ Colony Forming Units, Arabinogalactan 1.243 g, fructooligosaccharides 700 mg, L-glutamine 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