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Manfort: testing a dietary supplement for improving semen quality in patients with low or no sperm count

Submission date
10/10/2020

Recruitment status
No longer recruiting

Registration date
16/10/2020

Overall study status
Completed

Last Edited
10/09/2021

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Recently dietary supplements composed from natural products extracted from medicinal herbs have been used for the improvement of sperm quality. This traditional method of treatment is safe, effective and low cost compared with drug treatment. This study will investigate the effectiveness of the Manfort supplement composed of natural extracts on patients with low sperm count or azoospermia (no sperm count).

Who can participate?
Adult male patients suffering from low sperm count or azoospermia.

What does the study involve?
The sperm quality of the patients will be compared before and after treatment with Manfort.

What are the possible benefits and risks of participating?
Semen quality may be improved. The Manfort supplement has not shown any side effects.

Where is the study run from?
Jannat Hospital (Egypt)

When is the study starting and how long is it expected to run for?
May 2018 to December 2020

Who is funding the study?
Egypt Innovate for Development and Training Foundation (Egypt)

Who is the main contact?
1. Mr Mahmoud Elnahas Hussein, elnahasinventor@gmail.com
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Study website

https://manfort.wuiltsite.com/about-us

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Hussein280218

Study information

Scientific Title

A dietary supplement for semen parameters quality improvement in low sperm count and azoospermia patients

Study objectives
Multi-active antioxidants and anti-inflammatory ingredients found in a prepared dietary supplement called "Manfort" can improve the semen quality of azoospermia patients. The polyphenols and flavonoids are the main ingredients in Manfort supplement. These active antioxidants significantly improve semen volume, sperm concentration and sperm motility after treatment compared with before treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/10/2020, the clinical ethical committee of Egypt Innovate for Development and Training Foundation (3 El-Molla street, El-Zahraa, 11782, Cairo, Egypt; +20 (0)1011011835; egyptedif@gmail.com), ref: Hus/51020

Study design
Single-center interventional before and after study

Primary study design
Interventional

Secondary study design
Before and after study design

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Semen quality improvement of patients with azoospermia and low sperm count

Interventions
A mixture of multi-active natural products, antioxidants, anti-inflammatory ingredients, and high-quality honey, called the 'Manfort supplement' will be used in this study.

Male patients will be selected at random from the Jannat Hospital infertility clinic using sub-sequentially numbered dark closed envelopes by an independent third party.

After informed consent, patients are divided into two groups. The first group contains patients with low sperm total count (17 million) and the second group contains with azoospermia (no sperm).

Two semen specimens will be collected by masturbation after 4 days of last sexual abstinence. The specimens will be processed for analysis within 1 h after ejaculation in the andrology laboratory of the hospital to keep the quality of the semen specimen according to World Health Organization sample collection criteria. Semen examinations will be applied to analyze semen parameters such as volume, sperm concentration/ml of semen, total sperm count/ejaculate, sperm motility and white blood cells count in the semen. Sperm motility percentage will be evaluated according to the World Health Organization standard criteria.

The data of these two groups (without treatment) will be considered as control data.

After 15 days from the first semen sample collection and over 4 months, both low sperm count and azoospermia patients will be given 5 g Manfort dietary supplement three times daily after each meal at home. During all periods of the treatment, all patients will be followed up using phone contact or emails.

After 4 months of treatment time, another two semen specimens will be collected from the patients.

The data of these two groups (after treatment with Manfort) will be considered as data of the treated groups.
Supplement dose: Manfort supplement (orally 5 g/three times/day for 4 months)

Intervention Type
Supplement

Primary outcome measure
Measured at baseline (pre-treatment) and 4 months (post-treatment) from two semen specimens collected by masturbation:
1. Semen volume (by weight [g])
2. Sperm concentration (hemacytometer)
3. Sperm motility (phase-contrast microscope)
4. Semen WBCs (high power field (HPF) using the hemacytometer slide and light microscope)

Secondary outcome measures
1. Liver function measured using spectrophotometric assay of alanine transaminase (ALT) and aspartate aminotransferase (AST)

Overall study start date
20/05/2018

Completion date
15/12/2020

Eligibility

Key inclusion criteria
1. Aged 36 to 46 years
2. Married
3. Low sperm total count: sperm concentration 17 million after two semen analysis tests

4. Azoospermia patients show spermatogonia cells in each semen analysis
5. Body weight ranging from 65 to 95 kg
6. All patients living in a geographic area where follow-up can be accomplished

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
15 male patients with low sperm total count (17 million) and 18 patients (n = 18) with azoospermia (no sperm)

Total final enrolment
33

Key exclusion criteria
1. Patients suffering from other diseases such as varicocele were exempted from this study
2. Patients characterized with Sertoli cell only syndrome or absence of spermatogonia
3. Patients who take medications are exempted from this study to prevent semen analysis disturbance
4. Signs of infection or fever

Date of first enrolment
10/07/2018

Date of final enrolment
01/11/2019

Locations

Countries of recruitment
Egypt

Study participating centre
Jannat Hospital
El-Safwa Tower
100 Takseem Elshorouk Street
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Sponsor information

Organisation
Egypt Innovate for Development and Training Foundation

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Sponsor type
Charity

Website
http://edif.com/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Egypt Innovate for Development and Training Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Additional documents will be available at a later time.

Intention to publish date
01/01/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/12/2019	16/02/2021	Yes	No