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Treament of impaired sperm quality with micronutrients

Submission date	Recruitment status	[_] Prospectively registered
14/08/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/10/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/12/2016	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Infertility is when a couple cannot get pregnant (conceive), despite having regular unprotected sex. 10-15% of reproductive-aged couples trying to achieve pregnancy remain childless. Nearly half of all cases of infertility are due to male infertility. Male infertility is caused by abnormal sperm. In 45% of subfertile or infertile men the cause is unknown. This condition is called idiopathic (oligo)±(atheno)±(terato)spermia (iOAT). There are reports showing that the supplement l-carnitine alone or in combination with other micronutrients improves sperm parameters (i.e., number, movement, shape of sperm). Micronutrients, often referred to as vitamins and minerals, are parts of the diet which are required by the body in small amounts. The aim of this study is to compare the short-term effects of a combination of eight micronutrients including l-carnitine versus l-carnitine alone on sperm parameters as a treatment for iOAT.

Who could participate?
Infertile men aged 20-60

What did the study involve?
Participants are allocated to one of two groups. Participants in group 1 are given l-carnitine twice a day for three months. Participants in group 2 are given a combination of eight micronutrients including l-carnitine 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 were the possible benefits and risks of participating?
Participants may benefit from improved sperm quality. No side effects are expected.

Where was the study run from?
Karl Landsteiner Institut für zellorientierte Therapie in der Gynäkologie (Austria)

When did the study start and how long did it run?
January 2004 to January 2014

Who was funding the study?
Investigator initiated and funded

Who is the main contact?
1. Prof. Dr Martin Imhof
2. Dr Markus Lipovac

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Protocol serial number
Sperm parameter protocol 1.03/2014

Study information

Scientific Title
Comparison of the effect of a combination of eight micronutrients versus a standard mono preparation on sperm parameters

Study objectives

To compare the short term effects of a combination of eight micronutrients including l-carnitine vs. a mono-substance (l-carnitine alone) on sperm parameters showing superoirity of the combination over the mono-substance concerning different semen parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics board of the General Teaching Hospital Korneuburg, Austria, 14/12/2004, No.5/2004

Study design
Double-centre prospective open-labelled non-randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Reduced reproductive capability in men presenting an unexplained (unidentified) abnormal semen analysis

Interventions
A total of 299 participants who met the inclusion criteria were invited to participate. Participant number 1 was allocated to group 1, participant number 2 to group 2, participant number 3 to group 1 etc, to receive treatment for three months with:
1. A mono-substance (500 mg l-carnitine/twice a day, n=156)
2. A combined compound (440 mg l-carnitine + 250 mg l-arginine + 40 mg zinc + 120 mg vitamin E + 80 mg glutathione + 60 µg selenium + 15 mg coenzyme Q10 + 800 µg folic acid/once a day, n=143; Profertil®, Lenus Pharma GmbH, Vienna, Austria)
Semen analysis was performed at baseline and after three months of treatment.

Intervention Type
Supplement

Primary outcome(s)
The following sperm parameters were analysed at baseline and after 3 months of treatment:
1. Sperm volume (ml)
2. Sperm density (mio/ml)
3. Overall, fast and slow progressive motility (expressed as %)
4. % of sperm with normal morphology
All parameters were defined according to WHO guidelines (4th edition). Sperm analysis was performed with an automatic, computer analysing system called Sperm Class Analyzer® CASA System, by MICROPTIC SL, company based in Barcelona, Spain.

Key secondary outcome(s))
N/A

Completion date

20/01/2014

Eligibility

Key inclusion criteria
1. Male
2. 20 to 60 years of age
3. Suffering from at least one year of subfertility
4. At least one recent pathological semen analysis result

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Azoospermia
2. Aspermia
3. Varicocele
4. Recent urogenital infections
5. Hormonal disorders.

Date of first enrolment
11/01/2004

Date of final enrolment
15/10/2013

Locations

Countries of recruitment
Austria

Study participating centre
IMI Kinderwunschklinik
Dorotheergasse 7
Vienna
Austria
1010

Study participating centre
Med 19 Study Center of Vienna
Grinzingerstrasse 83
Vienna
Austria
1190

Sponsor information

Organisation
Karl Landsteiner Institute of Cell-Based Treatment in Gynecology (Karl Landsteiner Institut für zellorientierte Therapie in der Gynäkologie)

ROR
https://ror.org/05r0e4p82

Funder(s)

Funder type
University/education

Funder Name
Karl Landsteiner Institute of Cell-Based Treatment in Gynecology (Karl Landsteiner Institut für zellorientierte Therapie in der Gynäkologie)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2016		Yes	No