Statistical analysis

Project title: Micronutrient Supplementation for Women With PCO-syndrome - Influence of Nutrition and Physiology on the Development of PCOS-typical Parameters

NCT number: N/A

Participants

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Sample size calculation:

Assuming a reduction of the mean AMH levels by 2 ng/ml at a standard deviation of 3 ng/ml and an alpha value of 0.05 and a power of 0.90, the paired t-test requires 26 patients per group. Due to the fact that the participants wish to conceive a child and have been diagnosed with sterility, a low drop-out rate can be expected. There is no reliable data on this or similar treatments that allow prediction of the chance to conceive. Due to the favourable benefit-to-risk profile, a 15% drop-out rate is assumed. This corresponds to 4 patients per group. Thus, the final sample size is calculated as 30 patients per group, which leads to a total study population of 60.

Parameters obtained during routine clinical examinations:

All parameters on outcome (AMH = anti-müllerian hormone, total testosterone and androstendion levels) will be obtained during routine clinical examinations.

Several additional parameters will also be collected and included in the database. They do not require additional effort on behalf of the patients. They include: general patient information (age, duration of infertility, height and body weight, additional medication); information pertaining to PCO-syndrome (menstruation history, Ferriman-Gallwey-score on hirsutism (if applicable), acne, scalp-hair effluvium); hormone parameters on days 2 to 5 of the menstrual cycle (androstendion, thyroid-stimulating hormone, luteal hormone, follicle-stimulating hormone, sex hormone binding globulin); as well as an oral glucose tolerance test, which is routinely performed by general practicioners.

In addition, the individual development of the fertililty treatment will be documented for a maximum of 6 months following active study participation.

The bio-statistician will randomise the data using nQuery advisorTM Version 7.0. The information will then be packaged in an envelope by a person independent of the participating medical professionals and other scientific personnel. This will only be opened after the inclusion of the patient. Categorical variables will be presented as absolute numbers and percentages, numerical variables as median and interquartile range.

Final statistical analysis:

The following statistical analyses are planned: The result parameters and the patient characteristics of the two groups will be compared using the Welch test (for numerical variables) and the Chi-square-test or Fisher's exact test (for categorical variables). A p-value of <0.05 is considered to be statistically significant. The analysis will be performed as an intention-to-treat analysis. The statistical analyses will be performed using SPSS 24.0 for Windows (SPSS Inc., 1989-2017).

Overview on parameters to be analysed:

Parameter	*Unit*	*Type*	*Planned statistical test*
Age	Years	Numerical	Welch test
Body mass index	Kg/m^2	Numerical	Welch test
Sterility: Secondary (versus primary)	n (%)	Categorical	Chi-square/Fisher's exact test
Duration of infertility	Years	Numerical	Welch test
Pre-treatment FSH	mU/mL	Numerical	Welch test
Pre-treatment LH	mU/mL	Numerical	Welch test
Pre-treatment AMH	ng/mL	Numerical	Welch test
Pre-treatment testosterone	ng/mL	Numerical	Welch test
Pre-treatment androstenedione	ng/mL	Numerical	Welch test
Post-treatment AMH	ng/mL	Numerical	Welch test
Post-treatment testosterone	ng/mL	Numerical	Welch test
Post-treatment androstenedione	ng/mL	Numerical	Welch test

Abbreviations used: n (%) = number (frequency)