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Press Release

BlueGnome's 24sure platform selected for two centre clinical study

ESHRE launches international study of polar body screening

The efficacy of preimplantation genetic screening (PGS) has been one of the most hotly-disputed subjects in assisted reproduction over the past few years. None of the trials carried out so far has shown conclusively whether it works or not. Now the ESHRE Task Force on PGS has decided to try to find out if a novel method of doing PGS, using polar body biopsy and chromosome array analysis, offers a possible solution.

Professor Joep Geraedts, ESHRE (*European Society of Human Reproduction and Embryology*) chairman, told the 25th annual conference of the society today that the Task Force would carry out a pilot study of PGS in one of each pair of 23 chromosomes in polar bodies, tiny cells that are a by-product of egg development, in collaboration with BlueGnome, a DNA technology company based in Cambridge, UK. Once a pilot study has shown that the technique is feasible, the researchers intend to carry out an international randomised trial.

The first phase will begin in September 2009 in two centres: University of Bonn, Germany (Dr. Markus Montag and Professor Hans van der Ven) and SISMER, Bologna, Italy (Dr. Luca Gianaroli and Dr. Cristina Magli). "Because this is a new technology", said Dr. Gianaroli, "we need to carry out a pilot study in order to be sure that the analysis can be completed within a time period that allows for fresh transfer, as well as to ensure the reliable identification of the chromosomal status of an oocyte in at least 90% of polar body biopsy attempts."

The two centres chosen for the pilot study have considerable experience in the field of polar body biopsy because legislation in their countries restricts the possibility of undertaking embryo biopsy at a later stage of development. The data from the study will be independently analysed by Dr. Sjoerd Repping, from the Academic Medical Centre in Amsterdam, who carried out a randomised trial of PGS on three-day old embryos published in 2007. The researchers hope to present the data at ESHRE 2010 in Rome and to start the RCT with the involvement of at least six centres in different European countries later the same year.

Oocytes to be used in the pilot phase will be obtained from volunteer patients who have given consent for their use in this study. There will be no age restrictions on those donating their eggs.

By biopsying polar bodies at an early stage of egg development, the researchers believe that not only are they using a less invasive method of chromosome analysis, but also a more accurate one. "A biopsied blastomere, or very early embryo, is not a true representation of the other cells in that same embryo", said Professor Joep Geraedts, ESHRE chairman. "This mosaicism confuses the analyses and we don't know what it means for that embryo in the later stages of its development."

24sure, the novel molecular technique to be used in both phases of the trial was developed by BlueGnome and is based on DNA amplification and microarray technology, which enables scientists to look at all the chromosomes at the same time. This is, in theory, far more powerful than the method of fluorescent in situ hybridisation or FISH which has been used thus far.

“It is because we think this subject is so important”, said Professor Geraedts, “that we have decided to launch our first-ever clinical study. We hope that we will be able to answer the outstanding questions about PGS once and for all. If we can show that polar body screening works, it will be a major step forward in improving IVF treatment for many women who have persistent difficulty in getting pregnant and maintaining a pregnancy.”

All BlueGnome products are supplied for Research Use Only.

About BlueGnome

BlueGnome (www.cytochip.com) is a specialist developer of microarrays, consumables, software and FISH probes to improve the speed and resolution of cytogenetic investigations.

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