



Stemagen First to Create Cloned Human Embryos from Adult Cells

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LA JOLLA, CA – Stemagen, a privately held embryonic stem cell research company, announced today it has become the first in the world to create, and meticulously document, a cloned human embryo using somatic cell nuclear transfer (SCNT).

Stemagen CEO Samuel H. Wood, M.D., Ph.D., a co-author of the publication and a donor of the cells from which the embryos were cloned, terms this achievement “a critical milestone in the development of patient-specific embryonic stem cells for human therapeutic use, potentially including developing treatments for Parkinson’s, Alzheimer’s and other degenerative diseases.” Stemagen’s research is exhaustively detailed in a paper published in today’s issue of the highly regarded peer-reviewed scientific journal *Stem Cells*.

“This is not merely a technical improvement on previous research in this area,” said Andrew French, Ph.D., lead author on the paper, “Development of Human Cloned Blastocysts Following Somatic Cell Nuclear Transfer (SCNT) with Adult Fibroblasts.”

“No other scientific group has documented the cloning of an adult human cell, much less been able to grow it to the blastocyst stage, the stage at which it is the adult donor cell that is driving embryonic development, the stage that yields the cells (the inner cell mass) from which embryonic stem cell lines are made,” said French, who is Stemagen’s Chief Scientific Officer.

Five blastocysts were developed from 25 donated mature oocytes. Three were confirmed to be clones based on DNA fingerprinting demonstrating the presence of the skin cell donor DNA in the blastocyst, while one was further confirmed to be a clone by an additional mitochondrial DNA (mtDNA) analysis which revealed the presence of oocyte donor mtDNA without any oocyte donor nuclear DNA. For technical reasons, the genetic material in the remaining two blastocysts did not amplify to the extent required for analysis, and so while it is likely they were clones, the evidence required to claim that with certainty was not present. Thus, in this study, cloned blastocysts were successfully created from approximately 10% of all mature donated oocytes, an unexpectedly high rate given past research in this field.

The oocytes used in this study were donated, without compensation, by egg donors and intended parents undergoing egg donation cycles for reproductive purposes at the Reproductive Sciences Center in La Jolla, a leading fertility center specializing in egg donation and other advanced assisted reproductive technologies.

"As important as stem cell research is, all of us involved in this study realized that our overriding responsibility was to the intended parents who entrusted us with their dream of having a child," said Catharine Adams, Ph.D., a co-author on the paper and the laboratory director for Reproductive Sciences Center. "We in the IVF laboratory felt comfortable in this collaboration because we have consistently achieved pregnancy rates of greater than 80% from these types of high quality egg donors. In this study, all the intended parents were successful in achieving a pregnancy."

Stemagen and the Reproductive Sciences Center worked closely, over an extended period of time, with a leading independent Institutional Review Board (IRB) to develop procedures ensuring that all parties received comprehensive informed consent and that procedures were in place to protect their confidentiality in the process. All research procedures, including the culturing of the skin cells (fibroblasts) were performed under clinical laboratory conditions in close cooperation with the Assisted Reproductive Technologies (ART) Laboratory of the Reproductive Sciences Center, directed by Catharine Adams, Ph.D. French notes, "An important reason for the success of our SCNT procedures depended on the close coordination between our laboratory personnel and fertility center laboratory staff. Timing is a critical element in maximizing the probability of success in this type of procedure."

Wood points out that this research was exhaustively scrutinized by some of the world's most respected scientists and underwent an exceptionally rigorous process of verification, "This achievement was so critical to our field, we felt we should spare no effort in the process of establishing the validity of our work."

DNA fingerprinting is the scientifically accepted method for determining if an embryo is a true clone. According to French, "All samples were subjected to this type of analysis to determine their true genetic makeup."

For that, the company turned to Genesis Genetics, a recognized worldwide leader in the field of reproductive embryonic analysis.

Company founder and CEO, Mark Hughes, M.D., Ph.D., said "We were proud to collaborate with Stemagen in this important accomplishment. As the leading provider of genetic diagnosis of human embryos, it was important for an independent company like Genesis Genetics to be involved in the verification of this achievement."

Stemagen, Inc., is dedicated to the production of patient-specific embryonic stem cells for therapeutic use through SCNT and "uniparental" embryonic stem cells technology.

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