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Acupuncture on the day of embryo transfer: a randomized controlled trial of 635 patients


Dorthe Andersen ^a, Kristine Løssl ^a, Anders Nyboe Andersen ^a,
Jeanette Fürbringer ^b, Helle Bach ^c, Jannie Simonsen ^d,
Elisabeth C Larsen ^{a,*}

^a The Fertility Clinics, Copenhagen University Hospital, Rigshospitalet, 2100 Copenhagen, Denmark; ^b The Fertility Clinics, Copenhagen University Hospital, Hvidovre Hospital, 2650 Hvidovre, Denmark; ^c The Fertility Clinics, Copenhagen University Hospital, Herlev Hospital, 2730 Herlev, Denmark; ^d The Fertility Clinics, Odense University Hospital, Sdr. Boulevard 29, 5000 Odense, Denmark

* Corresponding author. E-mail address: elisabeth.clare.larsen@rh.regionh.dk (E.C. Larsen).



Dorthe Andersen graduated from Nursery school at Herlev Hospital, University of Copenhagen in 1992. Since December 2000 Dorthe has been working at The Fertility Clinic, The Juliane Marie Centre, Rigshospitalet. In 2004 she passed the Acupuncturist exam (Traditional Chinese Medicine) as well as a research course for nurses.

Abstract This prospective, randomized, controlled and double-blinded trial studied whether acupuncture in relation to embryo transfer could increase the ongoing pregnancy rates and live birth rates in women undergoing assisted reproductive therapy. A total of 635 patients undergoing IVF or intracytoplasmic sperm injection (ICSI) were included. In 314 patients, embryo transfer was accompanied by acupuncture according to the principles of traditional Chinese medicine. In the control group, 321 patients received placebo acupuncture using a validated placebo needle. In the acupuncture group and the placebo group, the ongoing pregnancy rates were 27% (95% CI 22–32) and 32% (95% CI 27–37), respectively. Live birth rates were 25% (95% CI 20–30) in the acupuncture group and 30% (95% CI 25–30) in the placebo group. The differences were not statistically significant. These results suggest that acupuncture administered in relation to embryo transfer has no effect on the outcome of IVF and ICSI. 

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Introduction

Since the randomized controlled trial by Paulus et al. (2002) suggested that acupuncture on the day of embryo transfer increased the pregnancy rate, the interest from healthcare

workers and patients has been huge. In the following years, several randomized controlled studies have showed a beneficial effect of acupuncture at the time of embryo transfer (Dieterle et al., 2006; Smith et al., 2006; Westergaard et al., 2006). The differences were irrespective of whether

the control group received sham acupuncture (i.e. needling at non-acupuncture points) or no treatment. Moreover, in a review from the Cochrane Collaboration (Cheong et al., 2008) the pooled results of six trials (Benson et al., 2006; Domar et al., 2009; Paulus et al., 2002, 2003; Smith et al., 2006; Westergaard et al., 2006), including a total of 1022 patients, showed a significantly higher clinical pregnancy rate favouring the use of acupuncture on the day of embryo transfer (OR 1.5, 95% CI 1.15–1.95). As regards live birth rate, only three trials were available for analysis (Paulus et al., 2002, 2003; Westergaard et al., 2006) but the meta-analysis confirmed a significant and beneficial effect on the live birth rate when acupuncture was performed on the day of embryo transfer (OR 1.86, 95% CI 1.27–2.73).

Recently however, the results from two other independent meta-analyses have been published (El-Toukhy et al., 2008; Manheimer et al., 2008). Manheimer and colleagues included seven randomized controlled trials comparing acupuncture either without acupuncture, sham acupuncture or placebo acupuncture (i.e. 'needling' at true acupuncture points but no penetration of the skin). As in the Cochrane analysis (Cheong et al., 2008), data from the control groups were pooled for the primary analysis. Similar to the earlier studies, Manheimer et al. (2008) demonstrated a significant improvement in the clinical pregnancy rate. On the contrary, El-Toukhy and colleagues (2008) could not demonstrate an increased clinical pregnancy rate when using the same seven studies as Manheimer et al. (2008), but in addition this analysis included a conference abstract where 94 women were randomized to either acupuncture or no treatment (Craig et al., 2007).

The purpose of the present study was to assess further – through a large randomized controlled and double-blinded trial – whether acupuncture could be used to increase the ongoing pregnancy and live birth rate using the validated Streitberger placebo acupuncture needle in the control group, thus simulating the acupuncture procedure using the same acupuncture points as in the acupuncture group but without penetrating the skin (Streitberger and Kleinhenz, 1998).

Materials and methods

Study design

This prospective randomized multicentre study was carried out in the period from October 2005 to October 2006 at four public Danish fertility clinics together performing more than 3000 cycles of IVF and intracytoplasmic sperm injection (ICSI) annually. Patients were consecutively informed verbally about the project at the start of hormonal stimulation. On the day of ovum retrieval, all couples were informed in writing about the project. They were also informed that participation in the study required available embryos for transfer and that each clinic could not include and randomize more than two patients per day. The regional ethical committee of Copenhagen and Frederiksberg, Denmark approved the study (no. KF01276193). Further the study was reported to ClinicalTrials.gov (ID NCT00913354)

Sample size calculations were based on an expected average ongoing pregnancy rate of 30% per embryo transfer.

Power calculations anticipated that a 10% difference in this endpoint between the true acupuncture and placebo acupuncture group would require approximately 325 patients in each group with a power of 80% and a *P*-value of 0.05.

Patients

The inclusion criteria were women ≤ 37 years of age, treatment with IVF/ICSI and transfer of one or two embryos in the first, second or third stimulated cycle. Embryo transfer was performed on the second or third day after ovum retrieval.

The exclusion criteria were patients treated with frozen and thawed embryos and patients who in the actual cycle already had received any kind of concomitant treatment, i.e. reflexology or acupuncture at a private clinic.

Written consent was given on the day of embryo transfer from patients who were willing to participate and who fulfilled the inclusion criteria.

Randomization

In order to minimize post-randomization drop-out, patients were randomized to either acupuncture or placebo acupuncture on the morning of embryo transfer when it was apparent that there were suitable embryos for transfer. All patients for transfer were informed that they should contact the clinic in the morning after 8.45 am in order to be informed about the status of their fertilization and embryo development, as well as on the availability of embryos for transfer. Patients called the clinic in random order. The capacity of performing acupuncture/placebo acupuncture was limited to two patients a day at each clinic. Therefore the first two patients that called were informed that they could participate if they wished to. In the case of a couple deciding not to participate, the next couple was asked. The laboratory technicians informed about the number of embryos and the embryo quality. The nurses had no access to this information, but exclusively took care of the clinical arrangements.

The sequence of cluster randomization was based on a computer-generated list. In each of the four clinics, for every group of 40 patients, 20 were randomized to acupuncture and twenty to placebo acupuncture. Nurses did the randomization with the sealed envelope technique and the procedure was performed blinded to both the patients and to the clinician who performed the embryo transfer.

Acupuncture

In the present study, acupuncture and placebo acupuncture was performed by nurses who were authorized professional acupuncturists (DA, HB, JF and JS) or by nurses who before initiation of the study had received thorough instruction and training by the four professional acupuncturists. The acupuncture points were chosen according to traditional Chinese medicine and were identical to the points used in the studies by Paulus et al. (2002) and Westergaard et al. (2006). They included DU20, M29, KS6, Mp8 and Le3 before embryo transfer and DU20, Co4, Mp10, M36 and Mp6 after embryo transfer. The same acupuncture points were used

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