



UNIVERSITY OF GOTHENBURG
THE SAHLGRENSKA ACADEMY

Abstract - Master Thesis Project, the Pharmacy Programme

Data management in a clinical trial of a medical device

Frida Boger, 2009

Introduction: Transvaginal Ultrasound Guided Oocyte Retrieval (TUGOR) is considered the most painful procedure during In-Vitro Fertilisation (IVF). For the purpose of oocyte pick-up (OPU), aspiration needles are used. Vitrolife Sweden AB has developed a new needle, Swemed Sence™, with a decreased diameter on the tip that punctures the vaginal wall. No studies for investigating if the utilisation of these needles decreases the pain experience have been performed.

Method: Vitrolife Sweden AB has performed a clinical trial with the primary hypothesis that Swemed Sence™ causes less pain during and after TUGOR compared to the conventional aspiration needle. The trial was carried out at four fertility clinics in Sweden, with totally 257 patients included. The study was single blinded and local randomisation of patients was implemented. The primary variable pain was estimated using Visual Analogue Scale (VAS), at paper Case Report Forms (pCRFs).

Result: The pCRFs were entered into a data base and all data was double-checked. An electronic archive was build up for the pCRFs. Further analysis of the entered data was performed.

Conclusions: The usage of pCRF instead of electronic Case Report Forms (eCRFs) increases the validity of the data in this particular trial. VAS is the most appropriate measuring device for the estimation of pain in this study. Pain is a subjective variable, and therefore constitutes a complex variable to analyze.

Key words: TUGOR, IVF, OPU, Aspiration needles, VAS, Pain, CRF, Data management