

QUALIMORPH - Embryo quality evaluation in Intra Cytoplasmic Sperm Injection (ICSI) cycles with Fertimorph system

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General

Identification

Detailed name Embryo quality evaluation in Intra Cytoplasmic Sperm Injection (ICSI) cycles with Fertimorph system

Sign or acronym QUALIMORPH

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL (22/12/2009)

General Aspects

Medical area Biology

Health determinants Iatrogenic

Others (details) Infertility

Keywords In Vitro Fertilization (IVF), FertiMORPH system, embryo quality, Intra Cytoplasmic Sperm Injection ICSI

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Collaborations	
Funding	
Funding status	Private
Details	Ferring SAS
Governance of the database	
Sponsor(s) or organisation(s) responsible	Ferring SAS
Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Not-repeated cross-sectional studies (except case control studies)
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is made on the basis of:	Another treatment or procedure
Database recruitment is carried out as part of an interventional study	No
Database objective	
Main objective	Evaluate the concordance between the embryo quality appreciated by the biologist according to his normal technique and according to the Fertimorph system
Inclusion criteria	Embryos coming from couples having the following characteristics: -Criteria linked to the woman: woman with normal

	response, all infertility etiologies, aged up to 36 years, maximum of one prior assisted reproduction technique (ART) cycle, current ART cycle with ICSI with ejaculated or frozen sperm, normal ovarian reserve (evaluated via hormone assays and where applicable by an antral follicle count), with a normal uterus and without hydrosalpinx. -Criteria linked to the spouse: diagnosed male infertility, where applicable normal male karyotype, -Criteria linked to the studied attempt: at least 5 mature (MII) oocytes retrieved, maximum of two embryos transferred.
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years)
Population covered	Sick population
Gender	Woman
Geography area	National
Detail of the geography area	Multi-center study - 7 centers in France: Besançon, Grenoble, Lille, Montpellier, Strasbourg, Toulouse, Brest
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2010
Date of last collection (YYYY or MM/YYYY)	2010
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	130
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Biological data

Clinical data (detail)	Direct physical measures Medical registration
Biological data (detail)	Number and quality of the ovocytes, fertilization parameters, number and quality of the embryos
Presence of a biobank	No
Health parameters studied	Others
Other (detail)	Biological parameters: embryo quality and development

Procedures

Participant monitoring	No
Links to administrative sources	No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Under discussion
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only