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

Scientific investigator(s) (Contact)

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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 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) ovocytes 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