



**FONDAZIONE
CASA SOLLIEVO DELLA SOFFERENZA**

**OSPEDALE I.R.C.C.S.
OPERA DI SAN PIO DA PIETRELCINA
SAN GIOVANNI ROTONDO**

**Unità di Ricerca in Aterosclerosi e Trombosi
Responsabile: Elvira Grandone M.D.**



The FIRST Registry

recurrent **F**ailures in
assisted **R**eproductive **T**echniques



Example: "Heart attack" AND "Los Angeles"

Search for studies:

Search

[Advanced Search](#) | [Help](#) | [Studies by Topic](#) | [Glossary](#)

Recurrent Failures in assisted Reproductive Techniques (The FIRST Registry)

This study is currently recruiting participants. (see [Contacts and Locations](#))

Verified February 2016 by Casa Sollievo della Sofferenza IRCCS

Sponsor:

Casa Sollievo della Sofferenza IRCCS

Information provided by (Responsible Party):

Elvira Grandone, MD, Head of Unit, Casa Sollievo della Sofferenza IRCCS

ClinicalTrials.gov Identifier:

NCT02685800

First received: February 10, 2016

Last updated: February 15, 2016

Last verified: February 2016

[History of Changes](#)

OBIETTIVI

- Definire tutte le possibili variabili in grado di influenzare l'esito nelle procedure di PMA
- Migliorare il management clinico delle donne con precedenti tentativi di PMA senza successo
- Valutare l'impatto della trombofilia, se disponibile!!!

PIANO DELLO STUDIO

Registro prospettico.

SAMPLE SIZE

624 donne (per ottenere una differenza di nati vivi tra trattate e non trattate di circa 8%, per una potenza statistica dell' 80% e una p : 0.05).

TIMETABLE

Inizio 1/10/2015, Fine 30/09/2018.

CRITERI DI INCLUSIONE

- 2 o più fallimenti d'impianto/perdita di gravidanze clinicamente accertate ottenute mediante PMA;
- Ciclo di PMA al momento dell'arruolamento nello studio;
- Consenso informato.

CRITERI DI ESCLUSIONE

- Ipofunzione ovarica;
- Patologie uterine;
- Idrosalpinge;
- Precedente inclusione nello studio.

OUTCOMES

- Gravidanze clinicamente accertate;
- Nati vivi;
- Complicanze ostetriche (aborto, MEF, Preeclampsia, IUGR, Distacco di placenta);
- Tromboembolismo venoso;
- Sindrome da iperstimolazione ovarica (OHSS).

ACTIVE CENTRES AUGUST 2016

- **Baldini D.** *Centro di Fecondazione Medicalmente Assistita MoMò Fertilife, Bisceglie, Italy*
- **Carone D.** *Center of Human Reproduction and Andrology (CREA), Taranto, Italy*
- **Iuliano A.** *San Carlo Hospital, Department of Obstetrics and Gynaecology, Potenza, Italy*
- **Luperto A.** *Centro PMA, Presidio Ospedaliero di Nardò, Nardò (Lecce), Italy*
- **Tiboni G.M.** *Department of Medicine and Aging Science, University of G. D'Annunzio, Chieti, Italy*
- **Totaro P.** *Centro PMA, Casa di Cura Santa Maria, Bari, Italy*

OTHER INTERESTED CENTRES

- **Bartolotti T.** *'ARTeBIOS', Centro Demetra, Lugo di Romagna (RA)*
- **Brenner B.** *Thrombosis and Hemostasis Unit, Department of Hematology, Rambam Health Care Campus, Haifa, Israel*
- **Gris J.C.** *Laboratoire et Consulatations d'Hématologie, CHU Nîmes, Nîmes, France*



Recurrent Failures in Assisted Reproductive Techniques

Prospective Registry

A potential benefit of low-molecular-weight heparin (LMWH) in improving ART outcomes, independently of the presence of thrombophilia, has been suggested (Grandone E. et al, PLoS One 2014; Dentali F. al., J Thromb Haemost. 2011; Nelson SM. Hum Reprod Update 2008).

It was hypothesised that heparin can modulate many physiological processes required for blastocyst apposition, adherence and implantation with a potential role in improving pregnancy rates and outcomes.

Several factors could be involved in this process: age, quality of the embryos, number of embryos transferred, success of embryo transfer and endometrial receptiveness.

Thrombophilia?





Recurrent Failures in Assisted Reproductive Techniques Prospective Register

During this study we will collect and evaluate clinical data regarding the first cycle in women with previous ART failures.

The impact of thrombophilia will be evaluated if available.





Recurrent Failures in Assisted Reproductive Techniques

Prospective Registry

Inclusion Criteria:

2 or more failures (or loss of clinical pregnancies) after ART

ART cycle at enrollment

ART cycle at enrollment

Exclusion Criteria:

Ovarian hypofunction

Uterine pathology

Hydrosalpinges



Recurrent Failures in Assisted Reproductive Techniques

Prospective Registry

Outcomes:

Clinical pregnancy

Live birth

Obstetric complications (Foetal loss, Intrauterine foetal death, Pre-eclampsia, Foetal growth restriction, Placental abruption)

Venous thromboembolism

OHSS



For the full protocol and details about data collection,
please contact us at the following address:
e.grandone@operapadrepio.it

mvillani27@libero.it

Tel: 0039(0)882416284

FAX: 0039(0)882204058

