

# **Preconception counseling during SARS-CoV2 (Covid19) pandemic**

Prospective observational study  
November 2020

**TITLE:** Preconception counseling during SARS-CoV2 (Covid19) pandemic

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# RESPONSIBILITY STATEMENT

## RESPONSIBILITY STATEMENT

By signing this protocol of the project entitled: Preconception counseling during SARS-CoV2 (Covid19) pandemic  
The undersigned affirm that:

- The study respects the ethical and legal norms applicable to this type of study and will follow the norms of good clinical practice in its conduct.
- They have the material and human resources needed to carry out the study, without interfering with the performance of other types of studies or with other clinical tasks that are usually assigned to it.
- They undertake that each subject is treated and controlled following the provisions of the protocol with a favorable opinion from the Ethics Committee for Clinical Research and other committees and authorities involved.
- The collaborators who are included in the study are adequately trained to carry it out, will have an active participation and consent to do it.

## MAIN RESEARCHER

Signed: \_\_\_\_\_

\_\_\_\_\_, \_\_\_\_ of \_\_\_\_\_ 20\_\_

Name: Manuel Gonçalves-Henriques

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## SENIOR TUTOR

Signed: \_\_\_\_\_

\_\_\_\_\_, \_\_\_\_ of \_\_\_\_\_ 20\_\_

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## **ABSTRACT**

A new Coronavirus emerged at the end of 2019 in Whuan, People's Republic of China, tainting a great number of individuals and causing a large number of deaths around the world – the SARS-CoV2, responsible for a disease called COVID19, declared pandemic in March 2020.

The infection by SARS-CoV2 is spread through respiratory goticules and its highly infectious. The range of its clinical symptoms is wide, going from asymptomatic individuals to serious illness and death.

Given that COVID 19 is a new entity, many concerns have been raised regarding pregnancy – the potential effects of the virus in mother and fetal well being, as well as the compatibility of treatments to more severe cases with pregnancy. Also, due to local and national lockdowns and the infection of health staff may eventually lead to inadequate prenatal medical care.

Facing a new infection with such a devastating potential, preconception counseling poses a great challenge.

This is a prospective observational study that aims to evaluate the position of the European Obstetricians when it comes to counsel their patients willing to achieve pregnancy during SARS-CoV2 pandemic.

## **KEYWORDS**

Coronavirus, Counselling, COVID19, pre-conception, Pregnancy Complications



## **AIMS**

### **PRIMARY AIM**

- The main aim of this work is to evaluate the position of the European Obstetricians when it comes to counsel their patients willing to achieve pregnancy during SARS-CoV2 pandemic.

### **SECONDARY AIMS**

- To evaluate the European obstetricians main concerns about pregnancy during the SARS-CoV2 pandemic.
- To evaluate the opinion of the European obstetricians opconcerning vaccination against SARS-CoV2 when pregnancy is planned.



# INTRODUCTION

## BACKGROUND

A new Coronavirus emerged at the end of 2019 in Whuan, People's Republic of China, tainting a great number of individuals and causing a large number of deaths around the world – the SARS-CoV2, responsible for a disease called COVID19. In March 2020, due to the devastating effects of this new infection, the World Health Organization (WHO) announced a worldwide pandemic in March 2020. Like different Coronavirus, SARS-CoV2 causes an acute respiratory syndrome (SARS) which may end in multiorgan failure and death. (1)

The infection by SARS-CoV2 is spread through respiratory droplets and is highly infectious. The range of its clinical symptoms is wide, going from asymptomatic individuals to serious illness and death. Older, obese and patients with comorbidities such as , diabetes mellitus, hypertension or other cardiovascular or respiratory disorders and immunosuppression are at higher risk of developing serious symptoms. (2,3)

Given that COVID 19 is a new entity, many concerns have been raised regarding pregnancy – the potential effects of the virus in mother and fetal well being, as well as the compatibility of treatments to more severe cases with pregnancy. (4) Some studies report a higher risk of minor changes in pregnant women such as mild lymphopenia or thrombocytopenia but in general it seems that pregnancy, in spite of being a state of immunosuppression, seems not to pose a specific risk for more serious illness. (5,6) There are few reports of perinatal transmission of the virus. Likewise, it's still not clear if the infection by SARS-CoV2 leads to higher rates of premature labor, premature rupture of membranes or surgical delivery. (7,8)

Also, due to local and national lockdowns and the infection of health staff may eventually lead to inadequate prenatal medical care. (9)

Facing a new infection with such a devastating potential, preconception counseling poses a great challenge.

## JUSTIFICATION FOR STUDY

This study will evaluate the opinion and the position of the European Obstetricians in a preconception scenario.

This study may help doctors worldwide to have a more robust position when it comes to counsel their patients during the pandemic. Also, this study will ascertain if there is a common position throughout Europe or if there are some differences between countries, which is a possible scenario given that this infection had a different impact on various countries and regions so far.

# **METHODS**

## **STUDY DESIGN**

- Prospective observational study based on inquiries

## **DATES**

- The collection of data will take 2 weeks after the research team is defined and the research project is started.

## **POPULATION OF REFERENCE**

- Obstetricians and residents in Obstetrics working in an European country

## **SELECTION CRITERIA**

- Obstetricians and residents in Obstetrics working in an European country

# STATISTICS

## DATABASE

The database will be rigorously defined with the variables intended to be analyzed based on the objectives set. The necessary information will be included in a database in Excel and SPSS format, where the variables to be analyzed will be detailed.

The data of this study will be anonymized, since the researcher will receive the data without any identification.

Finally, and prior to the statistical study, an exploratory data analysis will be carried out to review the quality of the information extracted.

## STUDY VARIABLES

### DEPENDENT VARIABLES

NAME	LABEL	TYPE	DESCRIPTION
<b>7</b>	counseling	Categoric	Question 7 – Opinion about getting pregnant
<b>8a</b>	Young and healthy patient	Categoric ordinal	Question 8 – How much would you agree with getting pregnant in this specific situation?
<b>8b</b>	Healthy patient over 40 years old	Categoric ordinal	Question 8 – How much would you agree with getting pregnant in this specific situation?
<b>8c</b>	Young immunosuppressed patient	Categoric ordinal	Question 8 – How much would you agree with getting pregnant in this specific situation?
<b>8d</b>	Young patient with chronic respiratory or cardiac pathology	Categoric ordinal	Question 8 – How much would you agree with getting pregnant in this specific situation?
<b>8e</b>	Young patient old undergoing assisted reproductive treatments (ART)	Categoric ordinal	Question 8 – How much would you agree with getting pregnant in this specific situation?
<b>8f</b>	Patient over 40 years old undergoing ART	Categoric ordinal	Question 8 – How much would you agree with getting pregnant in this specific situation?
<b>8g</b>	Patient with poor obstetric history (history of repeated abortions or late fetal dismiss)	Categoric ordinal	Question 8 – How much would you agree with getting pregnant in this specific situation?
<b>9a</b>	Higher risk of miscarriage	Dicotomic (0,1)	Question 9 – Is this factor a major concern?
<b>9b</b>	Higher risk of preterm birth	Dicotomic (0,1)	Question 9 – Is this factor a major concern?
<b>9c</b>	Higher risk of caesarean delivery	Dicotomic (0,1)	Question 9 – Is this factor a major concern?
<b>9d</b>	Teratogenic risk of the virus	Dicotomic (0,1)	Question 9 – Is this factor a major concern?

<b>9e</b>	Higher severity of maternal infection	Dicotomic (0,1)	Question 9 – Is this factor a major concern?
<b>9f</b>	Increase risk of maternal medical complications	Dicotomic (0,1)	Question 9 – Is this factor a major concern?
<b>9g</b>	Risk of neonatal infection	Dicotomic (0,1)	Question 9 – Is this factor a major concern?
<b>9h</b>	Less likely to breastfeed	Dicotomic (0,1)	Question 9 – Is this factor a major concern?
<b>9i</b>	Less availability of medical assistance during pregnancy	Dicotomic (0,1)	Question 9 – Is this factor a major concern?
<b>10a</b>	Vaccine during pandemic	Dicotomic (0,1)	Question 10 – Would you recommend a vaccine before pregnancy?
<b>10b</b>	Vaccine after pandemic	Dicotomic (0,1)	Question 10 – Would you recommend a vaccine before pregnancy?

### INDEPENDENT / CONTROL VARIABLES

NAME	LABEL	TYPE	DESCRIPTION
<b>sex</b>	Gender	Dicotomic (0,1)	Gender
<b>age</b>	Age	Numeric (discrete)	Age (years)
<b>years</b>	Years in Obstetrics	Numeric (discrete)	Years of Work in Obstetrics (years)
<b>categ</b>	Professional Category	Dicotomic (0,1)	Resident / Specialist
<b>country</b>	Country of work	Categoric	Country where person works
<b>field</b>	Field of Expertise	Categoric	Field of main routine clinical activity

### SAMPLE SIZE / STUDY POWER

- Not applicable - As much answers as possible

### STATISTICAL ANALYSIS

- Means, standard deviations, percentages
- T-test to compare groups concerning continuous variables
- Chi-square to compare proportions
- Linear / Multiple regression to compare continuous variables

## **STUDY PLAN**

1. Submission to ENTOG approval
2. Submission to ENTOG Multicentric Research groups
3. Recruitment of adjuvant researchers.
4. Translation of the questionnaire to national languages of adjuvant researchers
5. Application of questionnaires (2 weeks)
6. Data retrieval and analysis
7. Redaction of results

## **ETHICAL CONSIDERATIONS**

As an observational study based on anonymous questionnaires applied to medical doctors, no ethical considerations are to be reported.

## **FINANCIAL SUPPORT**

No need for financial support

## **SIDE COSTS**

No expected side costs, if any, the main researcher will be in charge.

## **PUBLICATION**

- The results may be presented in scientific meetings and/or published in scientific journals or other social media.

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