COVID-19 Information

Public health information (CDC)

Research information (NIH)

SARS-CoV-2 data (NCBI)

Prevention and treatment information (HHS)

Español

NIH U.S. National Library of Medicine

ClinicalTrials.gov

COVID-19 Vaccine and Ovarian Reserve

ClinicalTrials.gov Identifier: NCT04748172

Recruitment Status : Recruiting
First Posted : February 10, 2021
Last Update Posted : March 26, 2021

See Contacts and Locations

Sponsor:
Sheba Medical Center

Information provided by (Responsible Party):
Dr. Aya Mohr-Sasson, Sheba Medical Center

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

Go to

Brief Summary:
As Israel is the first country to widely vaccinate its population using the mRNA vaccine against COVID-19, evaluating its influence on ovarian reserve is essential .

Condition or disease	Intervention/treatment
Fertility Issues Vaccine Adverse Reaction	Biological: SARS-CoV-2 virus vaccines Diagnostic Test: AMH sampling

Show detailed description

Study Design

Go to

Study Type :
Observational

Estimated Enrollment :
200 participants

Observational Model:
Case-Control

Time Perspective:
Prospective

Official Title:
The Effect of COVID -19 mRNA Vaccine on Ovarian Reserve

Actual Study Start Date :
February 1, 2021

Estimated Primary Completion Date :
February 2022

Estimated Study Completion Date :
February 2022

Groups and Cohorts

Go to

Group/Cohort	Intervention/treatment

Group/Cohort	Intervention/treatment
Study Group: Women who are planning to be vaccinated Women that are planning to be vaccinated, before receiving the first shot of the vaccine	Biological: SARS-CoV-2 virus vaccines mRNA SARS-CoV-2 virus vaccines (By Pfizer or Moderna) Diagnostic Test: AMH sampling Blood sample for AMH on recruitment and after three months
Control Group: Women who are not planning to be vaccinated Women visiting other ambulatory clinics that are not planning to be vaccinated	Diagnostic Test: AMH sampling Blood sample for AMH on recruitment and after three months

Outcome Measures

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Primary Outcome Measures :

1. Delta in AMH levels [Time Frame: From first vaccination untill the second AMH sampling - after three month]

   AMA levels on recruitment minos AMH levels after three months

Biospecimen Retention: Samples Without DNA
Blood samples evaluated for Anti Mullarian Hormone (AMH)

Eligibility Criteria

Go to

Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years to 42 Years (Adult)

Sexes Eligible for Study:

Female

Gender Based Eligibility:

Yes

Gender Eligibility Description:

Women in reproductive age

Accepts Healthy Volunteers:

Yes

Sampling Method:

Non-Probability Sample

Study Population

Reproductive age women (age 18 to 42) that are planning to be vaccinated in Israel

Criteria

Inclusion Criteria:

- Age 18-42
- No previous exposure to covid-19 vaccine (first or second dose)
- No known past Covid-19 infection

Exclusion Criteria:

- Premature ovarian failure
- Endometriosis
- Polycystic ovary syndrome
- Pregnancy
- Fertility treatment

Contacts and Locations

Go to

Information from the National Library of Medicine

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04748172***

Locations

Israel

Sheba Medical Center **Recruiting**

Ramat-Gan, Israel, 56506

Contact: Dr. A Mohr-Sasson, M.D 97235302777 ext 97235302777 mohraya@gmail.com

Contact: Aya Mohr- Sasson, M.D 0523692906 mohraya@gmail.com

Sponsors and Collaborators

Sheba Medical Center

More Information

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Publications of Results:

Anifandis G, Messini CI, Daponte A, Messinis IE. COVID-19 and fertility: a virtual reality. Reprod Biomed Online. 2020 Aug;41(2):157-159. doi: 10.1016/j.rbmo.2020.05.001. Epub 2020 May 8.

Joguet G, Mansuy JM, Matusali G, Hamdi S, Walschaerts M, Pavili L, Guyomard S, Prisant N, Lamarre P, Dejucq-Rainsford N, Pasquier C, Bujan L. Effect of acute Zika virus infection on sperm and virus clearance in body fluids: a prospective observational study. Lancet Infect Dis. 2017 Nov;17(11):1200-1208. doi: 10.1016/S1473-3099(17)30444-9. Epub 2017 Aug 23.

Percivalle E, Zavattoni M, Fausto F, Rovida F. Zika virus isolation from semen. New Microbiol. 2017 Jul;40(3):197-198. Epub 2017 May 17.

Khomich OA, Kochetkov SN, Bartosch B, Ivanov AV. Redox Biology of Respiratory Viral Infections. Viruses. 2018 Jul 26;10(8). pii: E392. doi: 10.3390/v10080392. Review.

Liu M, Chen F, Liu T, Chen F, Liu S, Yang J. The role of oxidative stress in influenza virus infection. Microbes Infect. 2017 Dec;19(12):580-586. doi: 10.1016/j.micinf.2017.08.008. Epub 2017 Sep 14. Review.

Agarwal A, Rana M, Qiu E, AlBunni H, Bui AD, Henkel R. Role of oxidative stress, infection and inflammation in male infertility. Andrologia. 2018 Dec;50(11):e13126. doi: 10.1111/and.13126. Review.

Dutta S, Majzoub A, Agarwal A. Oxidative stress and sperm function: A systematic review on evaluation and management. Arab J Urol. 2019 Apr 24;17(2):87-97. doi: 10.1080/2090598X.2019.1599624. eCollection 2019. Review.

Homa ST, Vassiliou AM, Stone J, Killeen AP, Dawkins A, Xie J, Gould F, Ramsay JWA. A Comparison Between Two Assays for Measuring Seminal Oxidative Stress and their Relationship with Sperm DNA Fragmentation and Semen Parameters. Genes (Basel). 2019 Mar 19;10(3). pii: E236. doi: 10.3390/genes10030236.

Kuhn JH, Li W, Choe H, Farzan M. Angiotensin-converting enzyme 2: a functional receptor for SARS coronavirus. Cell Mol Life Sci. 2004 Nov;61(21):2738-43. Review.

Reis FM, Bouissou DR, Pereira VM, Camargos AF, dos Reis AM, Santos RA. Angiotensin-(1-7), its receptor Mas, and the angiotensin-converting enzyme type 2 are expressed in the human ovary. Fertil Steril. 2011 Jan;95(1):176-81. doi: 10.1016/j.fertnstert.2010.06.060. Epub 2010 Aug 1.

Wang J, Peng Y, Xu H, Cui Z, Williams RO 3rd. The COVID-19 Vaccine Race: Challenges and Opportunities in Vaccine Formulation. AAPS PharmSciTech. 2020 Aug 5;21(6):225. doi: 10.1208/s12249-020-01744-7. Review.

Vartak A, Sucheck SJ. Recent Advances in Subunit Vaccine Carriers. Vaccines (Basel). 2016 Apr 19;4(2). pii: E12. doi: 10.3390/vaccines4020012. Review.

Responsible Party:

Dr. Aya Mohr-Sasson, Principal Investigator, Sheba Medical Center

ClinicalTrials.gov Identifier:

NCT04748172 History of Changes

Other Study ID Numbers:

8121-21-SMC

First Posted:

February 10, 2021 Key Record Dates

Last Update Posted:

March 26, 2021

Last Verified:

February 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

Undecided

Plan Description:

On request

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Keywords provided by Dr. Aya Mohr-Sasson, Sheba Medical Center:

Ovarian reserve

Corona-19 virus

SARS-CoV-2

Additional relevant MeSH terms:

Infertility