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Health in mothers and children after assisted reproductive technology - Committee of Nordic ART and Safety (CoNARTaS)

Submission date
23/10/2018

Recruitment status
No longer recruiting

Registration date
28/12/2018

Overall study status
Ongoing

Last Edited
07/01/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
More than 7 million children have been born after assisted reproductive technology (ART) since the first baby was born after ART in 1978. The significant decrease in twin births has caused a tremendous drop in the twin birth rates and the associated preterm birth rate. However, single births conceived by ART also have a slightly higher risk of adverse outcomes depending on the ART technology used. The aim of this study is to assess the short- and long-term health risks in children conceived after ART.

Who can participate?
Women who delivered after ART treatment and children born after ART conception in 1985-2015 in Sweden, Norway, Denmark and Finland, and women delivering after spontaneous conception during the same time period and their children

What does the study involve?
This study only includes only register data that are routinely recorded in all private and public clinics in Denmark. This data recording is compulsory and there is no other involvement for the patients. The main categories of data are type of ART treatment, pregnancy and perinatal outcomes, selected diagnosis from specialised health care including detailed information on malignancies, diabetes, imprinting diseases, cardiovascular diseases, neurodevelopmental health and school performance and causes of death.

What are the possible benefits and risks of participating?
Possible benefits are the new knowledge obtained, which may lead to altering or abandoning certain ART methods such as freezing and lead to more safe ART treatments. Further if increased long-term health risks are seen in ART children screening programs may be set up for the patients to prevent further disease development. There are no risks for patients related to the trial.

Where is the study run from?
1. Fertility Clinic, Rigshospitalet (Denmark)

2. National Institute for Health and Welfare (Finland)
3. Hvidovre Hospital (Denmark)
4. Helsinki University Hospital (Finland)
5. Sahlgrenska University Hospital, Inst of Clinical Sciences, University of Gothenburg (Sweden)
6. Norwegian University of Science and Technology (NTNU) (Norway)

When is the study starting and how long is it expected to run for?
October 2016 to October 2028

Who is funding the study?
1. NordForsk
2. Sahlgrenska Universitetssjukhuset
3. NFOG fund
4. Reprounion EU/Interreg
5. The Research Fund of Helsinki University Hospital
6. Kreftforeningen
7. Helse Midt-Norge
8. Norges Teknisk-Naturvitenskapelige Universitet

Who is the main contact?
Prof. Anja Pinborg

Study website
http://www.conartas.com

Contact information

Type(s)
Scientific

Contact name
Prof Anja Pinborg

ORCID ID
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Contact details
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2100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
706005

Study information

Scientific Title
Health in mothers and children after assisted reproductive technology - Committee of Nordic ART and Safety (CoNARTaS)

Acronym
CoNARTaS

Study objectives
Short- and long-term health in children conceived by assisted reproductive technology and in their mothers differs from health in children and mothers after spontaneous conception. Specific ART methods influence short and long-term health in children and mothers differently and give rise to altered health risk profiles.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approvals for data retrieval and linkage were obtained in each country. In Denmark and Finland, ethical approval is not required for research solely based on registry data. In Norway, ethical approval was given by the Regional Committee for Medical and Health Research Ethics (REC North, 2010/1909-13-20, 05/09/2016). In Sweden approval was obtained from the Ethical committee in Gothenburg, Dnr 214-12 (22/05/2012), T422-12, T516-15, T233-16, T300-17, T1144-17, T121-18.

Study design
Nordic controlled register-based cohort study including all children born after assisted reproductive technology and their mothers in Finland, Norway, Sweden and Denmark from 1985 to 2015. Control groups comprise the national birth cohorts born during the same period in the four Nordic countries, as well as their mothers.

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied

Reproductive medicine, infertility
Morbidity, cognitive development, and mortality in mothers and children after assisted reproductive technology treatment

Interventions
The cohort consists of 173,148 children conceived by ART and their mothers, identified from the Medical Birth Registries in Denmark (1994 to 2015), Finland (October 1992 to 2015), Norway (1984 to 2015) and Sweden (1985 to 2015). The control cohorts are the background populations of children born during the same time periods in the four countries and their mothers.

Data are individual-level data on all residents that are routinely collected by the national health and socio-economic registries in each country and may be linked using the unique personal identity number of each resident.

Main categories of data are on type of ART treatment herein IVF, ICSI, frozen embryo transfer and oocyte donation, pregnancy and perinatal outcomes, selected diagnosis from specialised health care including detailed information on malignancies, diabetes, imprinting diseases, cardiovascular diseases, neurodevelopmental health and school performance and causes of death are available for all individuals in the cohort.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Short and long-term health in children born after ART (perinatal outcomes, imprinting diseases, diabetes, pubertal diseases, malignancies, cardiovascular diseases, cognitive development, mental health, mortality)
2. Short and long-term health in women who give birth after ART (pregnancy complications, mental health, metabolic diseases, cardiovascular disease, cancer, mortality)

Data are routinely collected by the national health and socio-economic registries in each country. Data are entered continuously in the database and the primary outcome will be measured at different child ages with the relevant statistical adjustments for this in the analyses.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/10/2016

Completion date
01/10/2028

Eligibility

Key inclusion criteria
1. Women who delivered after ART treatment and children born after ART conception 1985-2015 in Sweden, Norway, Denmark and Finland
2. Control group: all mothers delivering after spontaneous conception during the same time period and their children

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
7,000,000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/1985

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Denmark

Finland

Norway

Sweden

Study participating centre
Fertility Clinic, Rigshospitalet
Blegdamsvej 9
Copenhagen
Denmark
2100

Study participating centre
National Institute for Health and Welfare
Mannerheimintie 166
Helsinki
Finland
FI-00271

Study participating centre
Dept Obstetrics/Gynecology, Hvidovre Hospital
Kettegaard Allé 30
Hvidovre
Denmark
2650

Study participating centre
Dept Obstetrics/Gynecology, Helsinki University Hospital
Haartmaninkatu 2
Helsinki
Finland
00029 HUS

Study participating centre
Dept Obst/Gynecology, Sahlgrenska University Hospital, Inst of Clinical Sciences, University of Gothenburg
Journalvägen 6
Gothenburg
Sweden
41685

Study participating centre
Department of Public Health and Nursing , Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology (NTNU)
Håkon Jarls Gate 11
Trondheim
Norway
7030

Sponsor information

Organisation
Fertility Clinic, Rigshospitalet

Sponsor details
Blegdamsvej 9
Copenhagen
Denmark
2100

Sponsor type
Hospital/treatment centre

Website
https://www.rigshospitalet.dk/afdelinger-og-klinikker/julianemarie/fertilitetsklinikken/Sider/default.aspx

ROR
https://ror.org/03mchdq19

Funder(s)

Funder type
Government

Funder Name
NordForsk

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Norway

Funder Name
Sahlgrenska Universitetssjukhuset

Alternative Name(s)
Sahlgrenska University Hospital, SU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Funder Name
NFOG fund

Funder Name
Reprounion EU/Interreg

Funder Name
The Research Fund of Helsinki University Hospital

Funder Name
Kreftforeningen

Alternative Name(s)
Norwegian Cancer Society, NCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Norway

Funder Name
Helse Midt-Norge

Alternative Name(s)
Central Norway Regional Health Authority

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Norway

Funder Name

Norges Teknisk-Naturvitenskapelige Universitet

Alternative Name(s)
Norwegian University of Science and Technology, The Norwegian University for Technology an Sciences, Universidad Noruega de Ciencia y Tecnología, NTNU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Results and Publications

Publication and dissemination plan
Results will be published in peer-reviewed high ranking scientific journals and at Nordic and international scientific congresses. Thirteen scientific publications have already been published based on the Nordic cohort data up to 2007 primarily on short term health outcomes i.e. perinatal morbidity and mortality and malformations. The trialists are now planning another 10 to 15 publications on long-term health outcomes including also the children born after ART conception up to 2015. Results of general interest will be published in the lay press, broadcast, television and social media.

Intention to publish date
01/01/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Anja Pinborg. As these are national health care data hosted in Statistics Denmark, data cannot be transported to other research institutions or hospitals.dk. Request for working with the database should be send to the investigator and the request will be brought up on the first coming CoNARTas board meeting. The board will look at each application individually. If approval is given the trialists will prepare a specific database for the purpose of the new study and researcher(s) will have login to Statistics Denmark with limited access to this specific role.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2011		Yes	No
Results article	results	01/09/2013		Yes	No
Results article	results	01/05/2014		Yes	No

Results article	results	01/09/2014		Yes	No
Results article	results	01/11/2014		Yes	No
Results article	results	01/03/2015		Yes	No
Results article	results	01/07/2015		Yes	No
Results article	results	01/10/2016		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	01/07/2018		Yes	No
Results article	results	01/10/2018		Yes	No
Results article	results	01/10/2018		Yes	No
Results article	results	01/01/2019		Yes	No
Results article	results	01/01/2020	27/01/2020	Yes	No
Results article	results	18/03/2021	11/01/2021	Yes	No
Results article		19/07/2021	01/06/2021	Yes	No
Results article		25/06/2021	28/06/2021	Yes	No
Results article		07/09/2021	08/09/2021	Yes	No
Results article		01/09/2022	02/09/2022	Yes	No
Results article		01/01/2025	07/01/2025	Yes	No