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A study assessing clinical aspects of pregnancy, delivery and perinatal outcomes in women with intrahepatic cholestasis of pregnancy

Submission date
01/06/2020

Recruitment status
No longer recruiting

Registration date
03/06/2020

Overall study status
Completed

Last Edited
23/04/2025

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
Intrahepatic cholestasis of pregnancy (ICP) is a condition that can occur in pregnancy which causes skin itching (pruritus), higher levels of serum (blood) bile acids, and increased rates of adverse perinatal (birth) outcomes. For the mother the outcome of ICP is usually benign, with pruritus resolving after the birth, but with a predisposition to hemorrhage (bleeding) before /during or after birth as a main cause of morbidity (illness) and mortality (death). Besides that, ICP is associated with an increased risk of morbidity and mortality for the baby, especially preterm birth, respiratory distress and stillbirth. The main option for the treatment of intrahepatic cholestasis of pregnancy is to improve maternal symptoms, normalize the biochemical markers and reduce the risks for the baby. This study aims to assess the diagnostic features, clinical aspects and perinatal outcomes of women with intrahepatic cholestasis of pregnancy.

Who can participate?
Pregnant women aged 18 and over with ICP, and a control group of pregnant women aged 18 and over without ICP

What does the study involve?
The study involves a conversation with the investigator based on a survey that includes questions about the medical history of the patient and questions about the onset of the symptom of ICP. Blood samples are also taken from each participant to investigate how ICP might cause premature birth, stillbirth, and postpartum hemorrhage.

What are the possible benefits and risks of participating?
As a general benefit, the results of this study will allow researchers to better understand and improve the management of women with intrahepatic cholestasis of pregnancy and reduce the risk of bleeding during and after birth. There were no harms or risks for the participants. No information that could identify the participant is collected. All information is provided on a voluntary basis.

Where is the study run from?
Nicolae Testemițanu State University of Medicine and Pharmacy (Moldova)

When is the study starting and how long is it expected to run for?
October 2019 to October 2023

Who is funding the study?
Nicolae Testemițanu State University of Medicine and Pharmacy (Moldova)

Who is the main contact?
Maria Cemortan
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
Intrahepatic cholestasis of pregnancy: diagnosis and perinatal outcomes

Study objectives

This study aimed to assess diagnostic features, clinical aspects and perinatal outcomes in women with intrahepatic cholestasis of pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/04/2020, Ethics Review Committee Nicolae Testemițanu State University of Medicine and Pharmacy (Bd. Stefan cel Mare si Sfant 165, Chisinau, MD 2004, Moldova; +373 (0) 22205701; contact@usmf.md), ref: 46

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Intrahepatic cholestasis of pregnancy

Interventions
Pregnant women are evaluated. The cases are divided into two groups: group 1, in which the pregnancy is complicated by ICP, and group 2 which covers the women without ICP.

The study involves a conversation with the investigator based on a survey that includes questions about the medical history of the patient, and questions about the onset of the symptoms of ICP. Blood samples are also taken from each participant to investigate how ICP might cause premature birth, stillbirth, and postpartum hemorrhage.

Outcomes are measured at the clinic visits and during admission for delivery up to the discharge of mother and infant.

Intervention Type
Other

Primary outcome measure

Composite outcome of perinatal morbidity and mortality, preterm delivery or neonatal admission for at least 4 hours; measured from patient medical notes between randomisation and 7 days post-delivery (death), or to discharge (neonatal unit admission)

Secondary outcome measures
1. Peak maternal serum concentration (between recruitment and delivery) of the following biochemical indices of disease:
1.1. Bile acids measured using blood test
1.2. Aspartate transaminase measured using blood test
1.3 Alanine transaminase measured using blood test
2. Vitamin K serum level measured using blood test
3. Prothrombin, fibrinogen, INR serum levels measured using blood test
4. Change of itch between recruitment and delivery, measured by the worst episode of itch over past 24 hours (mm on visual analogue scale, assessed at clinic visits)
5. Mode of delivery classified as spontaneous vaginal, instrumental vaginal or caesarean
6. In utero fetal death after recruitment
7. Preterm delivery – less than 37 weeks' gestation
8. Known neonatal death up to 7 days
9. Birth weight (g)
10. Newborn assessed using Apgar Score at 1 and 5 minutes postpartum
11. Gestational age at delivery
12. Estimate maternal blood loss at delivery
Measured from patient medical notes where not otherwise stated at the clinic visits and during admission for delivery up to the discharge of mother and infant

Overall study start date
15/10/2019

Completion date
15/10/2023

Eligibility

Key inclusion criteria
1. ICP (pruritus with a raised serum bile acid above 10 µmol/l) for the main group
2. Absence of ICP (absence of pruritus and normal serum bile acid (below 10 µmol/l)) for the control group
3. At least 22+0 weeks of gestation on day of recruitment
4. No known lethal fetal anomaly
5. Aged 18 years or over
6. Able to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned sample size 50 for each group

Total final enrolment
88

Key exclusion criteria
1. Women with known liver disease: acute viral hepatitis, autoimmune hepatitis, Wilson's disease, primary sclerosing cholangitis, primary biliary cirrhosis, symptomatic cholelithiasis, cytomegalovirus, Epstein-Barr virus, acute fatty liver of the pregnancy, drug-induced hepatitis
2. Women diagnosed with preeclampsia, HELLP syndrome and congenital thrombophilia

Date of first enrolment
01/06/2020

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
Moldova

Study participating centre
Mother and Child Institute
str. Burebista, 93
Chisinau
Moldova
MD2062

Study participating centre
Hospital no. 1
str. Melestiu, 20
Chisinau
Moldova
MD2001

Sponsor information

Organisation
Nicolae Testemițanu State University of Medicine and Pharmacy

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Sponsor type
University/education

Website
https://usmf.md/

ROR
https://ror.org/03xww6m08

Funder(s)

Funder type
University/education

Funder Name
Nicolae Testemițanu State University of Medicine and Pharmacy

Results and Publications

Publication and dissemination plan
The study results are planned to be published in 2024.

Intention to publish date
01/02/2024

Individual participant data (IPD) sharing plan
The datasets used and/or analyzed during the current study will be available upon request from Maria Cemortan (maria.cemortan@usmf.md). Data files with fully anonymized data, both raw data and subscales for each measure along with some basic demographic data will be available from January 2025 for at least 5 years (indefinitely if it is possible to formally archive). Data will be made available to researchers who have ethical approval to conduct studies that are in line with the original aims of the study. Consent from participants has been given for this, and none of the data will be identifiable.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/04/2025	23/04/2025	Yes	No