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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
maria.cemortan@usmf.md

# Contact information

### Type(s)
Public

### Contact name
Mrs Maria Cemortan

### Contact details
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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
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

## Study type(s)
Diagnostic

## 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(s)
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)

## Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Female

### 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

**ROR**
https://ror.org/03xww6m08

# Funder(s)

**Funder type**
University/education

**Funder Name**
Nicolae Testemițanu State University of Medicine and Pharmacy

# Results and Publications

## 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |