

# How migration affects health during childbirth and anesthesia: a study

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<b>Registration date</b> 25/09/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/09/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study explores the “healthy-migrant effect,” which suggests that migrants might be healthier than the local population. We aim to see if this is true in Greece by comparing the health outcomes of Greek women and migrant women giving birth in Athens. We will look at the risks of complications for mothers and babies.

### Who can participate?

- Recently migrated pregnant women who have been in Greece for 3 years or less and are giving birth in Athens.
- Women of Greek origin giving birth in Athens.
- All births from 22 weeks of pregnancy or from infants weighing 500 grams or more.

### What does the study involve?

Participants’ childbirth outcomes will be examined through both past medical records and ongoing observations. We will compare the health of Greek women and migrant women, focusing on factors like maternal characteristics, use of pain relief during childbirth, and prenatal care.

### What are the possible benefits and risks of participating?

None

### Where is the study run from?

‘Helena Venizelou’ General, Maternity and Children’s Hospital in Athens, Greece.

### When is the study starting and how long is it expected to run for?

January 2023 to December 2024.

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Dr. Konstantina Kalopita, [ntikal@hotmail.com](mailto:ntikal@hotmail.com)

# Contact information

## Type(s)

Public, Scientific, Principal investigator

## Contact name

Dr Konstantina Kalopita

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

Nil known

# Study information

## Scientific Title

Understanding the healthy migrant effect in the context of anaesthetic and perinatal challenges: an ambispective observational study

## Study objectives

We hypothesize that migrant women may experience poorer perinatal health outcomes compared to Greek native women. However, we expect to find that refugees carry less pregnancy comorbidities, experience more vaginal deliveries with less medical interventions compared to their Greek counterparts of higher maternal age who may, more often undergo in vitro fertilization (IVF). Moreover, better birth outcomes with fewer preterm births and low birth weight infants are expected among the refugee population. These results may be even more surprising given the anticipated underutilization of prenatal care visits of migrants in the host country. We expect that the findings of our study will be consistent with previous reports of the healthy immigrant effect on perinatal outcomes of refugees and will be applied to the Greek context as well.

## Ethics approval required

Ethics approval required

### **Ethics approval(s)**

approved 13/09/2023, 'Helena Venizelou' General, Maternity and Children's Hospital (2 Venizelou Square, Athens, GR 11521, Greece; +30-2132051125; quality-secr@hospital-elena.gr), ref: 19968/13-09-2023

### **Study design**

Ambispective observational study

### **Primary study design**

Observational

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Healthy-migrant effect or migrant health paradox

### **Interventions**

An ambispective observational study will be used including both a retrospective chart review and a prospective study design in order to compare perinatal, maternal and neonatal outcomes among refugee women and native women of Greek origin giving birth in a tertiary obstetric referral center in Athens, Greece.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Measured by retrospective chart review:

1. Maternal pathology:

Maternal comorbidities will include Gestational Diabetes Mellitus (GDM), hypertensive disorders (preeclampsia/eclampsia), smoking during pregnancy, HIV, hepatitis, anaemia and other health problems.

2. Anaesthetic data: General/CSE/spinal for caesarean delivery, epidural analgesia during labor

3. Maternal and neonatal outcomes:

3.1. Maternal outcomes will include postpartum haemorrhage, maternal transfusion, mother requiring HDU/ICU admission.

3.2. Neonatal outcomes will include 5-minute Apgar score <7, stillbirth rates, preterm birth ( $\leq 37$  weeks), intrauterine growth retardation (IUGR), emergency intubation of the newborn in OR, meconium-stained amniotic fluid, congenital abnormalities, Neonatal Intensive Care Unit admission/Special Care Baby Unit admission/Ward, perinatal mortality

### **Key secondary outcome(s)**

Measured by retrospective chart review:

1. Provision of neuraxial anaesthesia during labour

2. Overall maternal satisfaction

### **Completion date**

31/12/2024

# Eligibility

## Key inclusion criteria

1. We will include internationally recently migrated pregnant women with a length of stay in Greece  $\leq 3$  years, giving birth in Athens and women of Greek origin.
2. All births from 22+0 weeks' gestation or from infants weighing  $\geq 500$  g during the study period.

## Participant type(s)

Patient, Other

## Healthy volunteers allowed

No

## Age group

All

## Lower age limit

14 years

## Upper age limit

54 years

## Sex

Female

## Key exclusion criteria

Pregnant women with incomplete data in the hospital registry database or those referred to another center due to maternal or infant issues

## Date of first enrolment

01/01/2023

## Date of final enrolment

31/12/2024

# Locations

## Countries of recruitment

Greece

## Study participating centre

'Helena Venizelou' General, Maternity and Children's Hospital

2 Venizelou Square

Athens

Greece

GR11521

# Sponsor information

## Organisation

'Helena Venizelou' General, Maternity and Children's Hospital

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request from Dr Konstantina Kalopita (e-mail: ntikal@hotmail.com). All de-identified/anonymised data will become available after the publication of the study results.

## IPD sharing plan summary

Available on request