

How migration affects health during childbirth and anesthesia: a study

Submission date 22/09/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/09/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/09/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" 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

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Konstantina Kalopita

ORCID ID

<http://orcid.org/0000-0002-7977-9939>

Contact details

2 Venizelou Square

Athens

Greece

GR 11521

+30 6944353918

ntikal@hotmail.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not applicable (retrospective study)

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 measure

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 (≤ 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

Secondary outcome measures

Measured by retrospective chart review:

1. Provision of neuraxial anaesthesia during labour
2. Overall maternal satisfaction

Overall study start date

01/01/2023

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 ≤ 3 years, giving birth in Athens and women of Greek origin.
2. All births from 22+0 weeks' gestation or from infants weighing ≥ 500 g during the study period.

Participant type(s)

Patient, Other

Age group

All

Lower age limit

14 Years

Upper age limit

54 Years

Sex

Female

Target number of participants

5000 - 6000

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

Sponsor details

2 Venizelou Square

Athens

Greece

GR11521

+30-2132051125

quality-secr@hospital-elena.gr

Sponsor type

Hospital/treatment centre

Website

<https://www.hospital-elena.gr/>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication to a peer-reviewed journal.

Intention to publish date

31/12/2030

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