Transfer of metformin into human breast milk and the plasma of breastfeeding children - A low intervention trial with biobanking of breast milk and plasma in Västra Götalandsregionen och i Region Örebro (Metformin Breast feeding study)

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### Administrative details

#### **EU PAS number**

EUPAS105190

Study ID

105191

**DARWIN EU® study** 

No

**Study countries** 

Sweden
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### **Study description**

The study has a low intervention trial design in the sense that breast milk and blood will be collected merely to study excretion of metformin into breastmilk and transferal to her child. Participation in the study will not decide or in any other way interfere with patients' treatment as prescribed by their physician. Only patients that already have been assigned treatment with metformin by their physician will be approached and asked for participation. Breast milk will be collected at two times during the visit, using an electric breast milk pump. Venous blood will be collected from the woman and from the infant. After centrifugation, plasma samples and breast milk sample will be aliquotaded, frozen at -80 degrees and stored at Biobank Väst and Örebro Biobank, respectively. When all samples have been collected, they will be transferred to Uppsala Biobank. Samples will be analysed for pharmacokinetic properties using mass spectrometry at the UDOPP Platform (Uppsala Drug Optimization and Pharmaceutical Profiling) at the Department of Pharmacy, Uppsala University. The primary objective is to determine the concentration of metformin in plasma of breast-fed infants of lactating women treated for T2D. A secondary objective is to determine the milk-to-plasma ratio in the women and, based on absolute infant dose (AID) and dosage of mother, the relative infant dose will be calculated. The primary endpoint is the concentration of metformin in the breastfeeding child's plasma 4h after maternal dose intake. The secondary endpoint is the concentration of metformin in breast milk at 0h (trough) and 2h after intake. The tertiary endpoint is the maternal plasma concentration of metformin at 0h (trough) and 2h after intake. The measure of drug levels in plasma and milk, will be carried out using a validated method consisting of high-performance liquid chromatography coupled with tandem mass spectrometry (HPLC-MS/MS).

#### Study status

### Ongoing

### Research institutions and networks

### Institutions

### **Uppsala University**

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Institution

Department of Obstetrics, Östra Sjukhuset Göteborg, Department of Obstetrics and Gynecology, University Hospital Örebro

### Contact details

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Primary lead investigator

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#### **Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 10/04/2019

#### **Study start date**

Planned: 15/01/2024

Actual: 01/06/2023

### Data analysis start date

Planned: 01/09/2024

### **Date of final study report**

Planned: 01/12/2024

## Sources of funding

• EU institutional research programme

### More details on funding

IMI-2JU, Grant nr. 821520

# Regulatory

Was the study required by a regulatory body?

No

### Is the study required by a Risk Management Plan (RMP)?

Not applicable

# Other study registration identification numbers and links

Approval ny the Swedish Ethical Review Authority, Number: 2023-02549-01.

# Methodological aspects

Study type

Study type list

### Study type:

Non-interventional study

### Scope of the study:

Other

### If 'other', further details on the scope of the study

Transfer of drug via breastmilk to infant

### Main study objective:

The primary objective is to determine the concentration of metformin in plasma of breast-fed infants of lactating women treated for T2D. A secondary objective is to determine the milk-to-plasma ratio in the women and, based on absolute infant dose (AID) and dosage of mother, the relative infant dose will be calculated.

# Study Design

### Non-interventional study design

Cohort

## Study drug and medical condition

#### Medical condition to be studied

Type 2 diabetes mellitus

# Population studied

#### Age groups

- Adults (18 to < 46 years)</li>
- Term newborn infants (0 27 days)

#### **Estimated number of subjects**

60

# Study design details

#### **Outcomes**

The primary endpoint is the concentration of metformin in the breastfeeding child's plasma 4h after maternal dose intake. The secondary endpoint is the concentration of metformin in breast milk at 0h (trough) and 2h after intake.

### Data analysis plan

The quantification of metformin concentrations in human milk and plasma will be made using LC-MS/MS bioanalytical method in accordance with a standard operating procedure. Measurement of metformin levels in milk and plasma will be carried out using a validated method consisting of highperformance liquid chromatography coupled with tandem mass spectrometry (HPLC-MS/MS).

### Data management

### **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### Data sources

### Data sources (types)

Other

### Data sources (types), other

Prospective patient-based data collection

# Use of a Common Data Model (CDM)

### **CDM** mapping

No

# Data quality specifications

### **Check stability**

**Check conformance** 

Unknown

### **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No