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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Study Ongoing

Administrative details

EU PAS number

EUPAS105190

Study ID

105191

DARWIN EU® study

No

Study countries

Sweden

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

Study institution contact

Mats Hansson mats.hansson@crb.uu.se

Study contact

mats.hansson@crb.uu.se

Primary lead investigator

Mats Hansson

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)
- 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 conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No