

# Transfer of prednisolone into human breast milk and plasma of breastfeeding children - A low intervention cohort study with biobanking of breast milk and plasma (PREDBANK)

**First published:** 13/03/2024

**Last updated:** 24/05/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000059

### Study ID

1000000059

### DARWIN EU® study

No

### Study countries

☐ Sweden

## Study description

The project has a low intervention trials design in the sense that breast milk and blood will be collected merely to study excretion of prednisolone 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 prednisolone by their physician will be approached and asked for participation. 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 prednisolone in the plasma of breast-fed infants of lactating women treated with prednisolone to reduce inflammation in a variety of conditions.

Secondary objectives are to determine concentration of prednisolone/prednisone in the breast milk and maternal plasma and the milk-to-plasma ratio in the mothers and to calculate the average daily infant dose (ADID) and relative infant dose (RID). A tertiary objective is to evaluate the cortisol levels in the infants.

The primary endpoint is the concentration of prednisolone in the breastfeeding child's plasma 2h after feeding an infant breast milk, with the feeding taking place at 1h following maternal dose intake. The secondary endpoints are the concentration of prednisolone and prednisone in breast milk at 1h after maternal dose intake and the maternal plasma concentration of prednisolone and prednisone at 1h after prednisolone intake. The tertiary endpoint is the concentration of cortisol in the infant blood.

The quantification of prednisolone concentrations in human milk and maternal and infant plasma will be made using LC-MS/MS bioanalytical method in accordance with a standard operating procedure.

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## Study status

Finalised

## Research institutions and networks

# Institutions

## Uppsala University

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

Mats Hansson [mats.hansson@crb.uu.se](mailto:mats.hansson@crb.uu.se)

Study contact

[mats.hansson@crb.uu.se](mailto:mats.hansson@crb.uu.se)

### Primary lead investigator

Mats Hansson

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/03/2021

Actual: 01/03/2021

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### Study start date

Planned: 06/03/2024

Actual: 06/03/2024

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### **Data analysis start date**

Planned: 02/12/2024

Actual: 12/03/2024

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

Planned: 31/12/2024

Actual: 12/03/2024

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## Sources of funding

- EU institutional research programme

## More details on funding

ConcePTION IMI-JU 2: 821520

## Study protocol

[Clinical trial protocol - Prednisolone redacted \(2\).PDF](#)(172.14 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

Not applicable

# Other study registration identification numbers and links

2023-508913-18-00

## Methodological aspects

### Study type

### Study type list

**Study type:**

Clinical trial

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**Study design:**

Low interventional clinical trial

**Main study objective:**

The primary endpoint is the concentration of prednisolone in the breastfeeding child's plasma 2h after feeding an infant breast milk, with the feeding taking place at 1h following maternal dose intake.

## Study Design

**Clinical trial regulatory scope**

Post-authorisation interventional clinical trial

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## Clinical trial types

Low-intervention clinical trial

## Study drug and medical condition

### Anatomical Therapeutic Chemical (ATC) code

(S01BA04) prednisolone

prednisolone

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### Medical condition to be studied

Rheumatoid arthritis

Inflammatory bowel disease

Systemic lupus erythematosus

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### Additional medical condition(s)

Myositis, psoriatic arthritis

## Population studied

### Short description of the study population

Mothers with newborn infants 6-8 weeks postpartum

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### Age groups

Adults (18 to < 46 years)

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### Special population of interest

Nursing women

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### Estimated number of subjects

30

## Study design details

## **Setting**

Breast milk and blood will be collected merely to study excretion of prednisolone into breastmilk and transferal to her child. Participation in the trial 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 prednisolone by their physician and made the choice to breastfeed, will be approached and asked for participation. All procedures for blood collection will follow established routines at the clinical sites.

The sampling will take place  $\approx$  6-8 weeks after birth at the designated clinic. At this time point it is estimated that there is nothing left from medication taken during pregnancy.

Women willing to participate in the study will be provided with detailed information about what this entails and provided with a written informed consent form, that they will sign and also ask their partners (the other care giver) to sign. They will bring the signed informed consent form with them to the sampling center.

Breast milk will be collected once 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 the breast milk sample will be shipped to Uppsala Biobank where it will be frozen and stored. Samples will be analysed for pharmacokinetic properties using mass spectrometry at the platform UDOPP, Department of Pharmacy, Uppsala University.

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## **Interventions**

Blood sampling from infants

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## **Data analysis plan**

Dosage of infant as Average Daily Infant Dose (ADID) in mg/kg/day will be estimated by using 200 mL/kg/day as a standard for daily milk intake in accordance with FDA guidelines for lactation studies (FDA Clinical Lactation

Studies May 2019): “While a 150 mL/kg/day estimated milk intake is a reasonable assumption to estimate daily infant dosage, greater volumes do occur in early infancy and often correlate to the time of most reported infant adverse drug events. Additional consideration should be given to estimates of infant risk based on a 200 mL/kg/day milk intake in early infancy”.

Relative infant dose (RID) will be calculated by dividing infant dosage (ADID) in mg/kg/day with maternal dosage in mg/kg/day, multiplied with 100 in order to get the percentage. It is estimated that a RID < 10% is considered safe for the infant (Bennet PN, Use of the monographs on drugs, Drugs and Human Lactation, 1996:67-74.).

The maternal prednisolone/prednisone milk to plasma ratio will be calculated by dividing drug concentration in the mother’s milk with the drug concentration of the mother’s plasma.

Prednisolone concentration in infant blood will be reported. Cortisol concentration in infant blood will be reported.

## 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.

### Use of a Common Data Model (CDM)



**CDM mapping**

No

Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

No